IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

THE CHILDREN'S HOSPITAL OF PHILADELPHIA, *Plaintiff* v. ORPHION THERAPEUTICS, INC., *Defendant.*	Civil No. JURY TRIAL DEMANDED

COMPLAINT

Plaintiff The Children's Hospital of Philadelphia ("CHOP"), by and through its undersigned counsel, brings this Complaint against Defendant Orphion Therapeutics, Inc. ("Orphion") and asserts as follows:

NATURE OF THE ACTION

1. This is an action for declaratory judgment and breach of contract. This action results from Orphion's breach of its commitments to CHOP under various agreements between the parties, including its assertion of baseless claims in an action against CHOP in the Supreme Court of New York (the "New York Action") despite Orphion's promise to bring any such claims in the courts of Philadelphia, Pennsylvania.

PARTIES

2. CHOP is a non-profit organization incorporated in Pennsylvania, with its principal place of business at 3401 Civic Center Blvd., Philadelphia, PA 19104.

3. Orphion is a Delaware corporation with its principal place of business in Great Neck, New York.

JURISDICTION AND VENUE

4. This Court has personal jurisdiction over Orphion because, at all relevant times, Orphion intentionally availed itself of the rights and privileges of conducting business in Pennsylvania and had regular and systematic contacts with Pennsylvania. This Court also has personal jurisdiction because the agreements at issue were negotiated and signed by CHOP in Pennsylvania and the injuries giving rise to the claims were sustained in Pennsylvania as a result of Orphion's conduct directed toward CHOP. This Court has personal jurisdiction over Orphion because it consented to this Court's exercise of jurisdiction over it in the agreements that are the subject of this action.

5. This Court has subject matter jurisdiction over the claims alleged herein pursuant to 28 U.S.C. § 1332(a) because this is an action between citizens of different states and the matter in controversy exceeds the sum or value of $75,000, exclusive of interest and costs. This Court also has jurisdiction pursuant to 28 U.S.C. § 1367. This Court also has jurisdiction over this case pursuant to 28 U.S.C. §§ 2201-2202.

6. Venue in this district is proper pursuant to at least 28 U.S.C. § 1391(b)(2). Venue is also proper because the parties contractually agreed to venue in the courts of Philadelphia, Pennsylvania.

FACTUAL BACKGROUND

7. CHOP is one of the world's largest and oldest children's hospitals and a major research institution. CHOP's mission is to transform its inventions and discoveries into safe and effective therapies and products that could help children throughout the world. To achieve this

mission, CHOP identifies partners who can commercialize its technologies by launching clinical trials and submitting the regulatory applications necessary to bring products to market and deliver its transformational inventions and discoveries to children.

CHOP and Orphion Enter into Multiple Agreements.

8. In the fall of 2018, CHOP and Orphion began discussions around Orphion obtaining rights to certain CHOP-developed technology. Thereafter, the parties entered into multiple agreements with each other.

9. In October 2019, the parties entered into an agreement entitled "The Children's Hospital of Philadelphia Patent License Agreement-Exclusive" (hereinafter, the "License Agreement"). A true and correct copy of the License Agreement is attached hereto as Exhibit 1 to Orphion's complaint in the New York Action attached herein at Exhibit A.

10. Under the terms of the License Agreement, Orphion promised to develop and commercialize multiple therapeutic technologies that CHOP researchers had invented, including through a TPP1 Retinal Program and an MPS-IIIa Program, and to achieve specific Milestones in each of these programs.

11. Specifically, for the TPP1 Retinal Program, Orphion promised in the License Agreement to submit an Investigational New Drug Application ("IND") with the U.S. Food and Drug Administration by March 2021, and to initiate clinical trials in that program by June 2021.

12. For the MPS-IIIa Program, Orphion promised in the License Agreement it would complete in vivo studies by February 2021 and submit an IND by March 2022.

13. Orphion also promised in the License Agreement that it would reimburse CHOP for expenses associated with prosecution and maintenance of licensed patents and patent applications.

14. In September 2020, the parties entered into an agreement entitled "Vector Purchase Agreement" (hereinafter, the "Purchase Agreement."). A true and correct copy of the Purchase Agreement is attached hereto as Exhibit 2 to the complaint in the New York Action at Exhibit A.

15. Under the terms of the Purchase Agreement, Orphion agreed to pay CHOP approximately $682,000 for, *inter alia*, "Material," i.e., a specific physical lot of viral vectors manufactured by CHOP and designated AAV2-CAG-TPP1. *See, e.g.*, Section 3.1 of the Purchase Agreement.

16. Orphion also agreed in the Purchase Agreement that any legal action involving the Purchase Agreement or the Material will be adjudicated in the courts residing in Philadelphia, Pennsylvania.

17. In October 2020, the parties entered into an agreement entitled "Sponsored Research Agreement" (hereinafter, the "Sponsored Research Agreement"). A true and correct copy of the Sponsored Research Agreement is attached hereto as Exhibit B.

18. Under the terms of the Sponsored Research Agreement, Orphion agreed to pay CHOP to conduct a research project involving two nonclinical studies related to the TPP1 Retinal Program.

19. Orphion also agreed in the Sponsored Research Agreement that the courts in Philadelphia, Pennsylvania are the sole and exclusive jurisdiction for any and all disputes concerning the subject of the Sponsored Research Agreement.

20. In December 2020, the parties entered into an agreement entitled "Research Service Agreement for Vector Production" (hereinafter, the "Research Service Agreement"). A

true and correct copy of the Research Service Agreement with partial exhibits is attached hereto as Exhibit C.

21. Under the terms of the Research Service Agreement, Orphion agreed to pay CHOP $167,492 to fill AAV2-TPP1 bulk drug substance and to perform specific testing on the substance.

22. Orphion agreed in the Research Service Agreement that any legal action involving or arising under the Research Service Agreement will be adjudicated in Philadelphia, Pennsylvania.

Orphion Breaches Its Obligations to CHOP Under Multiple Agreements.

23. In the years that followed, Orphion failed to satisfy promises under each of these agreements.

24. Orphion failed to pay over $500,000 owed to CHOP for the Materials under the Purchase Agreement.

25. As a result of this failure, on August 16, 2023, CHOP gave formal notice to Orphion of breach of the Purchase Agreement.

26. CHOP terminated the Purchase Agreement effective September 17, 2023.

27. Orphion also failed to meet its obligations to CHOP under the License Agreement. It did not pay for expenses associated with the preparation, filing, prosecution, and maintenance of CHOP intellectual property as required under the License Agreement. It did not use reasonable best efforts to bring the Licensed Products or Licensed Processes to Practical Application. It failed to meet Milestones as required under the License Agreement, including by not filing an IND with the U.S. Food and Drug Administration for the TPP1 Retinal Program by March 2021, and by not filing an IND for the MPS-IIIa Program by March 2022.

28. As a result of these failures, on June 9, 2023, CHOP gave formal notice to Orphion of breach of the License Agreement.

29. CHOP terminated the License Agreement after the expiration of the notice period effective September 7, 2023.

30. Orphion failed to pay $79,111.20 owed to CHOP under sections 4.1 and 4.2 of the Sponsored Research Agreement for services provided by CHOP under that agreement.

31. Orphion failed to pay monies owed to CHOP under section 4.2 of the Research Service Agreement for services provided by CHOP under that agreement.

32. As a result of this failure, on November 3, 2023, CHOP gave formal notice to Orphion of breach of the Research Service Agreement.

33. CHOP terminated the Research Service Agreement effective February 2, 2024.

Orphion Files an Action Against CHOP in New York State Court Involving the Parties' Purchase Agreement and Its Material.

34. On October 2, 2024, Orphion commenced an action against CHOP in the Supreme Court of New York.

35. In the New York Action, Orphion asserted five counts against CHOP: Breach of Contract (First Cause of Action), Breach of the Confidentiality Provisions of the License Agreement (Second Cause of Action), Breach of the Implied Covenant of Good Faith and Fair Dealing (Third Cause of Action), Fraud (Fourth Cause of Action), and Conversion (Sixth Cause of Action). For each of the claims against CHOP in the New York Action, Orphion alleged damages exceeding $75,000.

36. Orphion spun a false tale in its complaint in the New York Action to avoid the consequences of its own failures to perform. It tried to recast itself as a victim of CHOP despite failing to perform under its various contracts with CHOP.

37. Orphion's claims against CHOP in the New York Action were premised on the fabricated assertion that CHOP breached the parties' agreements and committed fraud by providing a company called Latus Bio. Inc., co-founded by CHOP Chief Scientific Strategy Officer Dr. Beverly Davidson, with the Material that Orphion failed to pay for under the Purchase Agreement, and with the patent rights that Orphion would not pay fees to maintain under the License Agreement. In fact, CHOP had not provided Latus with the Material, and had not licensed to Latus the patents that CHOP licensed to Orphion.

38. Orphion alleged in the New York Action that CHOP's actions regarding the Material and performance under the Purchase Agreement purportedly caused Orphion's lack of performance under the License Agreement, and purportedly rendered invalid CHOP's termination of the License Agreement.

39. Each claim that Orphion asserted against CHOP in the New York Action involves the Purchase Agreement and/or the Material.

40. Orphion's count for Breach of Contract (First Cause of Action) in the New York Action involves the Purchase Agreement and/or the Material. Orphion alleges CHOP breached both the Purchase Agreement and the License Agreement. *See, e.g.*, Ex. A ¶¶ 92-104. The alleged breach of the Purchase Agreement involves the Purchase Agreement. The alleged breach of the License Agreement rests on the asserted factual predicate that CHOP's License Agreement termination was invalid because its grounds were caused by CHOP's purported breach of the Purchase Agreement. *Id.* ¶¶ 101-102; *see also id.* ¶ 10 ("CHOP breached the Purchase Agreement and then used its breach of the Purchase Agreement as a basis for terminating the License Agreement.").

41. Orphion's count for Breach of the Confidentiality Provisions of the License Agreement (Second Cause of Action) in the New York Action involves the Material of the Purchase Agreement. Orphion alleges that CHOP breached confidentiality obligations under the License Agreement by sharing Orphion's information with Latus. *See, e.g.*, Comp. ¶¶ 105-112. The alleged confidential information at issue involves the Material that is the subject of the Purchase Agreement. *See, e.g.*, Ex. A ¶¶ 5-6 (alleging that "Vector Material" was the subject of the Purchase Agreement); *id.* ¶ 110-111 ("Orphion provided CHOP and Davidson with confidential reports and data on work that Orphion did . . . including audits and ancillary work on the quality and usability of *the cGMP Vector Materials* to satisfy regulatory authorities . . . . [Dr. Davidson] and CHOP . . . shared Orphion's confidential reports and data with Latus . . . ." (emphasis added); *id.* ¶¶ 86-93 ("[H]ighly confidential trade secrets . . . provided to CHOP pursuant to the License Agreement" includes "work on the *Vector Materials*," "preclinical work on the use of the *Vector Materials* in animal studies," and "Orphion's ideas for auditing and using the cGMP *Vector Materials* in a manner that would gain regulatory acceptance." (emphases added)).

42. Orphion's count for Breach of the Implied Covenant of Good Faith and Fair Dealing (Third Cause of Action) in the New York Action involves the Purchase Agreement and the Material. The core of the claim is that "CHOP informed Orphion that it would not be delivering the 416 vials of cGMP Vector Materials that Orphion had purchased" under the Purchase Agreement, and that "CHOP's breach of the Purchase Agreement, therefore, made it impossible for Orphion to continue to operate as a viable business." *See, e.g.*, Ex. A ¶¶ 118, 120. Orphion alleges that CHOP breached the implied covenant of good faith and fair dealing because

CHOP allegedly caused the purported grounds for its termination of the License Agreement when it purportedly breached the Purchase Agreement. *See, e.g., id.* ¶ 121.

43. Orphion's count for Fraud (Fourth Cause of Action) in the New York Action involves the Purchase Agreement and its Material. This claim is based on the allegation that CHOP made false statements or omissions regarding the availability of the Material contracted for in the Purchase Agreement. *See, e.g.,* Ex. A ¶¶ 127-131.

44. Orphion's count for Conversion (Sixth Cause of Action) in the New York Action involves the Purchase Agreement and its Material. In this claim, Orphion alleges a property right to the Material based on the Purchase Agreement, and alleges that CHOP converted the Material by delivering it to Latus. *See, e.g.,* Ex. A ¶¶ 143-147.

45. By bringing an action in New York with claims against CHOP that involve the Purchase Agreement and its Material, Orphion breached Section 14.1 of the Purchase Agreement, in which Orphion agreed that "[a]ny legal action involving this [Purchase] Agreement, or the Material will be adjudicated in the courts residing in Philadelphia, Pennsylvania."

46. As a result of Orphion's breach of the Purchase Agreement, CHOP has incurred more than $75,000 in legal fees and costs to defend itself in the New York Action.

47. Orphion's claims against CHOP in the New York Action are without merit.

48. CHOP satisfied all of its obligations under the Purchase Agreement.

49. CHOP satisfied all of its obligations under the License Agreement.

50. Under the Purchase Agreement, CHOP was under no obligation to make Materials available to Orphion for which Orphion did not pay.

51. CHOP did not provide the Material to Latus.

52. CHOP's alleged non-performance under the Purchase Agreement did not cause Orphion's material breaches of the License Agreement, did not cause CHOP's grounds for termination of the License Agreement, and did not render CHOP's termination of the License Agreement invalid.

53. Contrary to Orphion's assertions, Orphion's own independent contractual breaches unrelated to CHOP's performance under the Purchase Agreement—*e.g.*, the failure to pay required patent fees and to meet development Milestones—provided valid bases for CHOP's termination of the License Agreement.

54. On December 17, 2025, CHOP moved to dismiss the New York Action on the grounds that, *inter alia*, Orphion's claims were brought in an improper venue.

55. On May 9**,** 2025, the New York court heard argument on CHOP's motion, made rulings on the record during the argument, and dismissed Orphion's claims against CHOP subject to the rulings set forth on the record of the argument. *See* Ex. D (Decision + Order on Motion in New York Action).

56. During the May 9, 2025 proceedings in the New York action, the Court stated on the record that "[i]f there's a dispute arising under the purchase agreement, [the Parties] designated a different forum as it relates to disputes which arise under that particular agreement." *See* Ex. E (Excerpts of Transcript of May 9, 2025 Proceedings in New York Action) at 18:11-14. The Court also stated that "I am of the view that the parties designated claims which arise under the purchase agreement to be governed by the purchase agreement, and the designation in the purchase agreement that claims arising under that agreement have to be litigated in the Commonwealth of Pennsylvania." *Id.* at 31:13-18.

COUNT I

DECLARATORY JUDGMENT: NO CHOP BREACH OF CONTRACT

57. CHOP restates and incorporates herein by reference the averments set forth in paragraphs 1 through 56 above.

58. Orphion contends that CHOP breached the Purchase Agreement.

59. CHOP did not breach any obligation to Orphion under the Purchase Agreement.

60. Orphion contends that CHOP breached the License Agreement.

61. CHOP's termination of the License Agreement was not invalid due to CHOP's purported breach of the Purchase Agreement or otherwise.

62. CHOP did not breach the License Agreement by terminating it or otherwise.

63. There is an actual controversy between CHOP and Orphion concerning at least whether CHOP breached the Purchase Agreement and License Agreement.

WHEREFORE, CHOP respectfully requests that the Court enter a judgment declaring that CHOP has not breached the Purchase Agreement or License Agreement, as alleged in the New York Action or otherwise.

COUNT II

DECLARATORY JUDGMENT: NO BREACH OF THE CONFIDENTIALITY PROVISIONS OF THE LICENSE AGREEMENT

64. CHOP restates and incorporates herein by reference the averments set forth in paragraphs 1 through 63 above.

65. Orphion contends that CHOP breached the confidentiality provisions of the license agreement.

66. CHOP did not breach section 9.9 or section 14.1 of the License Agreement, or any other section of the License Agreement, by sharing Orphion confidential information regarding the Material of the Purchase Agreement or otherwise.

67. There is an actual controversy between CHOP and Orphion concerning at least whether breached the confidentiality provisions of the License Agreement.

WHEREFORE, CHOP respectfully requests that the Court enter a judgment declaring that CHOP has not breached the confidentiality provisions of the License Agreement, as alleged in the New York Action or otherwise.

COUNT III

DECLARATORY JUDGMENT: NO BREACH OF THE IMPLIED COVENANT OF GOOD FAITH AND FAIR DEALING

68. CHOP restates and incorporates herein by reference the averments set forth in paragraphs 1 through 67 above.

69. Orphion contends that CHOP breached the implied covenant of good faith and fair dealing in the License Agreement.

70. CHOP did not breach any obligation to Orphion under the Purchase Agreement.

71. CHOP's termination of the License Agreement was not invalid due to CHOP's purported breach of the Purchase Agreement or otherwise.

72. CHOP did not breach the implied covenant of good faith and fair dealing in the License Agreement by purportedly causing grounds for termination of the License Agreement through breach of the Purchase Agreement, or otherwise.

73. There is an actual controversy between CHOP and Orphion concerning at least whether CHOP breached an implied covenant of good faith and fair dealing in the License Agreement.

WHEREFORE, CHOP respectfully requests that the Court enter a judgment declaring that CHOP has not breached the implied covenant of good faith and fair dealing in the License Agreement, as alleged in the New York Action or otherwise.

COUNT IV

DECLARATORY JUDGMENT: CHOP IS NOT LIABLE FOR FRAUD

74. CHOP restates and incorporates herein by reference the averments set forth in paragraphs 1 through 73 above.

75. Orphion contends that CHOP committed fraud upon Orphion.

76. CHOP made no intentional false statement or omission to Orphion relating to the Purchase Agreement or its Material, or otherwise, that Orphion reasonably relied upon to its detriment.

77. CHOP has not committed fraud.

78. There is an actual controversy between CHOP and Orphion concerning at least whether CHOP committed fraud.

WHEREFORE, CHOP respectfully requests that the Court enter a judgment declaring that CHOP has not committed fraud as alleged in the New York Action or otherwise.

COUNT V

DECLARATORY JUDGMENT: NO CONVERSION

79. CHOP restates and incorporates herein by reference the averments set forth in paragraphs 1 through 78 above.

80. Orphion contends that CHOP committed conversion with regard to the Material of the Purchase Agreement.

81. Orphion has not paid for the Material under the Purchase Agreement.

82. Orphion has no property right in Material for which it has not paid.

83. CHOP did not provide Latus with the Material.

84. CHOP did not commit the tort of conversion with respect to the Material or otherwise.

85. There is an actual controversy between CHOP and Orphion concerning at least whether CHOP committed conversion.

WHEREFORE, CHOP respectfully requests that the Court enter a judgment declaring that CHOP has not committed conversion as alleged in the New York Action or otherwise.

COUNT VI

BREACH OF CONTRACT

86. CHOP restates and incorporate herein by reference the averments set forth in paragraphs 1 through 85 above.

87. The Purchase Agreement, Sponsored Research Agreement, and Research Service Agreements are valid and enforceable contracts.

88. CHOP has performed all of its material obligations under the Purchase Agreement, Sponsored Research Agreement, and Research Service Agreement.

89. Orphion has willfully and materially breached the Purchase Agreement, including at least section 14.1 of the Purchase Agreement by asserting an action involving the Purchase Agreement and its Material in New York State Court.

90. Orphion has willfully and materially breached sections 4.1 and 4.2 of the Sponsored Research Agreement by failing to pay required amounts thereunder.

91. Orphion has willfully and materially breached section 4.2 of the Research Service Agreement by failing to pay required amounts thereunder.

92. CHOP has suffered considerable economic harm, including attorneys' fees and costs, in excess of $75,000 as a direct and proximate result of Orphion's breaches.

PRAYER FOR RELIEF

WHEREFORE, CHOP requests the following relief:

A. a judgment declaring that CHOP is not liable to Orphion under the Purchase Agreement;

B. a judgment declaring that CHOP is not liable to Orphion under the License Agreement;

C. a judgment declaring that CHOP is not liable to Orphion for breach of the implied covenant of good faith and fair dealing;

D. a judgment declaring that CHOP is not liable to Orphion for fraud;

E. a judgment declaring CHOP is not liable to Orphion for conversion;

F. damages in an amount to be determined at trial and more than $75,000 as a result of Orphion's breaches of the Purchase Agreement, Sponsored Research Agreement, and the Research Service Agreement;

G. reasonable attorneys' fees, costs, and expenses;

H. prejudgment interest; and

I. such other relief as is appropriate.

JURY DEMAND

CHOP demands a trial by jury on all issues so triable.

Dated: June 17, 2025

/s/ *John V. Gorman*
John V. Gorman (PA Bar No. 80631)
Bradie R. Williams (PA Bar No. 327334)
MORGAN, LEWIS & BOCKIUS LLP
2222 Market Street
Philadelphia, PA 19103
(215) 963-5000
john.gorman@morganlewis.com
bradie.williams@morganlewis.com

Attorneys for Plaintiff The Children's Hospital of Philadelphia

JS 44 (Rev. 04/21)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

The Children's Hospital of Philadelphia

(b) County of Residence of First Listed Plaintiff Philadelphia
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Morgan, Lewis & Bockius LLP
2222 Market Street, Philadelphia, PA 19103-3007
(215)(963-5000

DEFENDANTS

Orphion Therapeutics, Inc.

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☒ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☒ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

INTELLECTUAL PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit (15 USC 1681 or 1692)
- ☐ 485 Telephone Consumer Protection Act
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C. § 1332, 28 U.S.C. § 2201, 28 U.S.C. §§ 2201-2202

Brief description of cause:
Declaratory judgment, diversity (breach of contract).

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
Jun 17, 2025

SIGNATURE OF ATTORNEY OF RECORD
s/ John V. Gorman (PA Bar ID 80631) Morgan, Lewis & Bockius LLP, 2222 Market Street, Philadelphia, PA 19103

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. **Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. **Origin.** Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statute.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service.

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

DESIGNATION FORM

Place of Accident, Incident, or Transaction: Philadelphia, PA

RELATED CASE IF ANY: Case Number:_____ Judge:_____

1. Does this case involve property included in an earlier numbered suit? Yes ☐
2. Does this case involve a transaction or occurrence which was the subject of an earlier numbered suit? Yes ☐
3. Does this case involve the validity or infringement of a patent which was the subject of an earlier numbered suit? Yes ☐
4. Is this case a second or successive habeas corpus petition, social security appeal, or pro se case filed by the same individual? Yes ☐
5. Is this case related to an earlier numbered suit even though none of the above categories apply? If yes, attach an explanation. Yes ☐

I certify that, to the best of my knowledge and belief, the within case ☐ **is** / ☒ **is not** related to any pending or previously terminated action in this court.

Civil Litigation Categories

A. Federal Question Cases:

- ☐ 1. Indemnity Contract, Marine Contract, and All Other Contracts)
- ☐ 2. FELA
- ☐ 3. Jones Act-Personal Injury
- ☐ 4. Antitrust
- ☐ 5. Wage and Hour Class Action/Collective Action
- ☐ 6. Patent
- ☐ 7. Copyright/Trademark
- ☐ 8. Employment
- ☐ 9. Labor-Management Relations
- ☐ 10. Civil Rights
- ☐ 11. Habeas Corpus
- ☐ 12. Securities Cases
- ☐ 13. Social Security Review Cases
- ☐ 14. Qui Tam Cases
- ☐ 15. Cases Seeking Systemic Relief ***see certification below***
- ☐ 16. All Other Federal Question Cases. *(Please specify)*:_____

B. Diversity Jurisdiction Cases:

- ☒ 1. Insurance Contract and Other Contracts
- ☐ 2. Airplane Personal Injury
- ☐ 3. Assault, Defamation
- ☐ 4. Marine Personal Injury
- ☐ 5. Motor Vehicle Personal Injury
- ☐ 6. Other Personal Injury (*Please specify*):_____
- ☐ 7. Products Liability
- ☐ 8. All Other Diversity Cases: *(Please specify)*_____

I certify that, to the best of my knowledge and belief, that the remedy sought in this case ☐ **does** / ☒ **does not** have implications beyond the parties before the court and ☐ **does** / ☒ **does not** seek to bar or mandate statewide or nationwide enforcement of a state or federal law including a rule, regulation, policy, or order of the executive branch or a state or federal agency, whether by declaratory judgment and/or any form of injunctive relief.

ARBITRATION CERTIFICATION (CHECK ONLY ONE BOX BELOW)

I certify that, to the best of my knowledge and belief:

☒ Pursuant to Local Civil Rule 53.2(3), this case is not eligible for arbitration either because (1) it seeks relief other than money damages; (2) the money damages sought are in excess of $150,000 exclusive of interest and costs; (3) it is a social security case, includes a prisoner as a party, or alleges a violation of a right secured by the U.S. Constitution, or (4) jurisdiction is based in whole or in part on 28 U.S.C. § 1343.

☐ None of the restrictions in Local Civil Rule 53.2 apply and this case is eligible for arbitration.

NOTE: A trial de novo will be by jury only if there has been compliance with F.R.C.P. 38.

EXHIBIT A

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

ORPHION THERAPEUTICS, INC., **Plaintiff,** **- against -** **THE CHILDREN'S HOSPITAL OF PHILADELPHIA; LATUS BIO, INC.; and BEVERLY L. DAVIDSON;** **Defendants.**	**Index No.** **SUMMONS**

To the above-named Defendants:

YOU ARE HEREBY SUMMONED and required to answer the attached complaint of the Plaintiff in this action and to serve a copy of your answer upon the attorneys for the Plaintiff at the address stated below.

If this summons with notice was personally delivered to you in the State of New York, you must serve the notice of appearance within 20 days after such service, excluding the day of service. If this summons was not personally delivered to you in the State of New York, you must serve the notice of appearance within 30 days after service of the summons is complete, as provided by law.

If you do not serve an answer to the attached complaint within the applicable time limitation stated above, a judgment may be entered against you, by default, for the relief demanded in the complaint.

Plaintiff designates New York County, Commercial Division, as the place of trial. The basis of venue is CPLR §§ 501 and 503(a).

Dated: New York, NY
October 2, 2024

SADIS & GOLDBERG LLP

/s/ Ben Hutman

By: Ben Hutman
Kathleen D. Reilly
551 Fifth Avenue, 21st Floor
New York, New York 10176
Telephone: (212) 573-6675
Email: bhutman@sadis.com

Attorneys for Plaintiff Orphion Therapeutics

To:
The Children's Hospital of Philadelphia
3401 Civic Center Blvd.
Philadelphia, PA 19104

Latus Bio, Inc.
c/o The Corporation Trust Company
Corporation Trust Center
1209 Orange St.
Wilmington, DE 19801

Beverly Davidson
The Children's Hospital of Philadelphia
Clinical Vector Core Facility
3501 Civic Center Blvd.
Philadelphia, PA 19104

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

ORPHION THERAPEUTICS, INC., **Plaintiff,** **- against -** **THE CHILDREN'S HOSPITAL OF PHILADELPHIA; LATUS BIO, INC.; and BEVERLY L. DAVIDSON;** **Defendant.**	**Index No.** **COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiff Orphion Therapeutics, Inc. ("Orphion") by and through its undersigned counsel, for its Complaint against The Children's Hospital of Philadelphia ("CHOP"), Latus Bio, Inc. ("Latus"), and Beverly L. Davidson ("Davidson") (together "Defendants"), hereby allege, upon knowledge as to its own acts and information belief as to all other matters, as follows:

PRELIMINARY STATEMENT

1. This case is about a major research institution, CHOP's, fraudulent and bad faith conduct in deliberately misleading a small startup therapeutics company, Orphion, in order to breach its exclusive licensing and sale contracts with Orphion. CHOP's conduct caused Orphion to shutter its operations, leaving children with a rare disease to suffer needlessly of blindness. CHOP lied and breached its agreements with Orphion at the direction of Davidson and Latus—a competing therapeutics company which Davidson founded and in which CHOP is an investor—which itself subsequently used the same licensed technology and material that Orphion had purchased.

2. Orphion was formed to research and develop novel gene therapies for the treatment of rare and serious genetic disorders. As with all companies in the pharmaceutical development

space, prior to commercialization, Orphion required approval from the U.S. Food and Drug Administration ("FDA") or other comparable foreign regulatory agencies for its therapeutics. Obtaining regulatory approval is a long and costly process that takes years and involves many steps, including, among others, submitting an Investigational New Drug ("IND") or foreign equivalent application to the regulatory agencies based on results from preclinical and clinical testing.

3. In the fall of 2018, Orphion engaged in initial discussions with Defendants CHOP and Davidson, among others, to obtain and acquire the rights to certain of CHOP's inventions and assets including, during later discussions, vials of Viral Vector SPK-1002 (AAV-TPP1; Lot A2FP1-A1804C-C) ("Vector Materials"), a hyper-specialized material manufactured by Davidson and her team through CHOP's Clinical Vector Core and Center for Cellular and Molecular Therapeutics.

4. Orphion required these rights and Vector Materials to develop a treatment for the blindness caused by Late Infantile Neuronal Ceroid Lipofuscinosis Disease (also known as Neuronal Ceroid Lipofuscinosis Type 2 Disease) ("CLN2 Disease"). CLN2 Disease is a rare, rapidly progressive, disorder affecting children as young as 2 years old, usually causing blindness by age 7. Although there is an FDA-approved therapeutic for aspects of the motor skill and intellectual deterioration, there is currently no treatment for the blindness caused by CLN2.

5. These initial and further discussions eventually led to the negotiation and execution of an initial, primary agreement, the Patent License Agreement-Exclusive, on or about October 28, 2019 ("License Agreement"). The License Agreement gave Orphion "an exclusive (even as to CHOP), transferable, sublicensable license" to CHOP's various patents and patent applications related to treating CNS disorders, and any products resulting from those patents and applications

(the "Licensed Patent Rights"). (Ex. 1 at §§2.11, 2.13, 3.1, Appx. A.) As originally contemplated, the License Agreement included the acquisition of the Vector Materials, but during negotiations, CHOP removed the acquisition of those Vector Materials from that agreement and requested that the purchase of the Vector Materials be covered by a separate Vector Purchase Agreement (the "Purchase Agreement" and together with the License Agreement, the "Agreements").

6. Through the Purchase Agreement, Orphion purchased "all of CHOP's right, title and interest" in the Vector Materials that CHOP had already manufactured with "current Good Manufacturing Practices" ("cGMP") for use in Orphion's early phase clinical trials. (Ex. 2 at preamble, §1.1.) Delivery was to be made upon request from Orphion. (*Id.* §3.1.)

7. Operating under the assumption that CHOP would act in good faith and comply with the terms of the Agreements, and provide the cGMP Vector Materials it had promised to Orphion, Orphion worked diligently and tirelessly in its IND-enabling activities, including spending years developing its therapeutics, running preclinical studies, and finding investors to support product development. Orphion often had to do so, despite dealing with substandard work and delivery of promised paperwork from CHOP. If approved, Orphion's CLN2 treatment would have been worth at least $100 million at approval, with additional projected revenues of at least $500 million in its first five years of sales. Indeed, even in its early stages—prior to significant progress in developing its treatment—Orphion was valued at over $27.2 million after its last round of investment in 2019.

8. The Defendants all knew that the Licensed Patent Rights and the Vector Materials Orphion acquired from CHOP were necessary for both Orphion's research activities and human clinical trials, as well as Orphion's continued viability as a therapeutics company. Indeed, the

parties had numerous communications about the plans and progress of Orphion in moving its CLN2 treatment forward.

9. Shockingly, on June 1, 2023, after Orphion indicated its readiness and need to move forward with clinical trials using the Vector Materials it had purchased, CHOP, through email, falsely informed Orphion that CHOP no longer had the necessary cGMP Vector Materials. Of course, without the Vector Materials, Orphion's clinical trials and CLN2 treatment were not viable. As Defendants knew, it was impossible to create new, replacement cGMP Vector Materials in a timely manner or at a reasonable cost.

10. A week later, in a shocking turn of bad faith, CHOP notified Orphion that it was terminating the License Agreement because CHOP believed that Orphion would not be able to bring its CLN2 treatment to "practical application." Thus, CHOP breached the Purchase Agreement and then used its breach of the Purchase Agreement as a basis for terminating the License Agreement. As the Defendants refused to engage with Orphion to discuss the situation, and CHOP refused to provide Orphion the acquired cGMP Vector Materials, Orphion was left with no choice but to abandon years of meticulously developed research and clinical activities leaving children to suffer blindness from CLN2 without hope for a cure. Orphion's value was completely destroyed.

11. In truth, CHOP was lying. The Vector Materials were not unavailable. They still existed and could have been delivered as required under the Purchase Agreement. Rather, Davidson had created another company, Latus, to makes its own CLN2 treatment and wanted to use—or had already started using—the cGMP Vector Materials and Licensed Patent Rights that CHOP had sold and licensed to Orphion. Davidson and Latus directed or convinced CHOP to breach the Purchase Agreement by fraudulently claiming that CHOP no longer had the Vector

Materials, and then utilize its fraud as a basis to improperly terminate the License Agreement so that Davidson and Latus could use the Vector Materials and the Licensed Patent Rights to develop their own CLN2 treatment.

12. After making the fraudulent representation that CHOP no longer had the Vector Materials and utilizing it as an improper basis to terminate the License Agreement—thereby breaching the License Agreement—CHOP provided the supposedly unavailable Vector Materials to Latus so that Latus could develop its own CLN2 treatment—thereby piggy-backing off of Orphion's work with the Licensed Patent Rights.

13. Not only did CHOP breach the Agreements in bad faith and deliver the Vector Materials to Latus so that Latus could develop its own CLN2 treatment, but CHOP became an investor in Latus. Indeed, Davidson is a founder and member of Latus' scientific advisory board.

14. CHOP acted fraudulently and in bad faith in breaching the Purchase Agreement and terminating the License Agreement; CHOP fraudulently misrepresented and omitted the truth of the state of the Vector Materials and CHOP's commitment to working with Orphion under the Agreements; Latus and Davidson tortiously interfered with the Agreements; CHOP and Latus stole the Vector Materials; and Latus and Davidson are engaging in theft of Orphion's trade secrets and unfair competition in developing their own CLN2 treatment.

15. As a result of Defendants' actions, not only has Orphion been rendered worthless, but it lost its expected value of more than $500 million with the success of its CLN2 treatment. And, worst of all, Defendants' actions have delayed the creation of an effective treatment for CLN2 blindness.

PARTIES

16. Plaintiff Orphion is a Delaware corporation with its principal place of business in Great Neck, New York. Orphion is a start-up life sciences company that develops novel gene

therapies for the treatment of rare and serious genetic disorders in order to improve patient quality of life.

17. Defendant CHOP is a Pennsylvania corporation with its principal place of business in Philadelphia, Pennsylvania.

18. Defendant Latus is a Delaware corporation with its registered office at 1209 Orange Street, Wilmington, DE 19801. Latus was formed on May 2, 2022 as LastAAV, Inc. and changed its name to Latus Bio, Inc. on February 13, 2023.

19. Defendant Davidson is a resident of Pennsylvania. She is the Chief Scientific and Strategy Officer at CHOP's Research Institute, and leads the Clinical Vector Core at CHOP where the Vector Materials were manufactured and stored. Davidson is also a co-founder of Latus and a member of Latus' scientific advisory board.

JURISDICTION AND VENUE

20. This Court has jurisdiction over Defendants pursuant to CPLR Sections 301 and 302(a) as Defendants have continuous and systematic contact with New York by transacting business within New York and committing tortious acts that caused injury in New York to Orphion, a New York-based company. As more fully alleged below, on numerous occasions, Defendants CHOP and Davidson contacted and communicated with Orphion, a company they knew was resident in New York. These contacts and communications took place over the course of several years. Further, Defendants CHOP and Davidson also engaged in numerous communications with Orphion executives who Defendants knew were in New York. CHOP executed agreements with Orphion that specifically recognized that Orphion was based in New York, constituting a years-long contractual relationship with a New York company. Invoices and letters sent by CHOP to Orphion under those agreements were sent to Orphion in New York, and payments made to CHOP under those agreements were made from and by Orphion in New York

21. And Latus and Davidson tortiously interfered with the contracts of Orphion, and engaged in unfair competition and the misappropriation of trade secrets of Orphion, causing Orphion injury in New York.

22. Additionally Section 15.5 of the License Agreement has a broad mandatory forum selection clause in which the Parties to the agreements agreed to New York law and the "exclusive jurisdiction" of New York courts. In particular Section 15.5 provides:

> **All disputes between the Parties** shall be governed by the laws of New York not withstanding any of that state's laws to the contract. All disputes between the **Parties** shall be governed by the laws of New York not withstanding any of that state's laws to the contrary, and without regard to principles of conflicts of laws; provided, however, the foregoing shall not apply to disputes arising out of or relating to intellectual property which shall be governed by applicable federal laws and/or laws of New York (without regard for principles of conflicts of laws) as they apply to the given situation. The **Parties** further expressly agree that the exclusive venue for the resolution of any such disputes (including intellectual property shall be the state and federal courts located in New York and that such courts shall have exclusive jurisdiction. The **Parties** hereby submit themselves to venue in New York and to the exclusive jurisdiction of such courts for such purposes. (Emphasis added)

23. Venue is proper in this Court pursuant to CPLR Sections 501 and 503, and Section 15.5 of the License Agreement, under which CHOP and Orphion "expressly agree[d] that the exclusive venue for the resolution of any such disputes (including intellectual property[)] shall be the state and federal courts located in New York and that such courts shall have exclusive jurisdiction. The Parties hereby submit themselves to venue in New York and to the exclusive jurisdiction of such courts for such purposes."

FACTUAL ALLEGATIONS

Orphion's Treatment for Children Suffering from CLN2 Disease

24. Orphion is a gene therapy start-up company developing treatments for ocular and central nervous system manifestations of rare diseases.

25. In 2018, after meeting with CHOP and Davidson, Orphion began developing a treatment for the ocular manifestations of CLN2 Disease (also known as Neuronal Ceroid Lipofuscinosis Type 2 Disease). CLN2 Disease is a rare, rapidly progressive, terminal disorder affecting children as young as 2 years old. In its classic form, CLN2 results in children being bedridden by 6 and blind by 7, ultimately culminating in death between ages 7 and 12.

26. While an FDA-approved therapeutic known as Brineura® has shown to be effective in slowing the loss of motor and intellectual function in children with CLN2, there is no cure for the deadly disorder, nor does Brineura provide any benefit for the vision loss and blindness associated with the disease. Orphion's therapeutic—a subretinal gene therapy that produces a lysosomal soluble enzyme tripeptidyl-peptidase 1 protein ("TPP1") ("Orphion's Pediatric Therapeutic")—would have been the first gene therapy for the treatment and prevention of the rapid loss of retinal tissue associated with CLN2 that results in childhood blindness.

27. Orphion also planned on developing a broader treatment for CLN2 and potentially other central nervous system ("CNS") diseases.

28. In 2019 and 2020—even before Orphion had made significant progress toward an IND application—Orphion raised funding for the company at a $27.2 million post-money valuation.

29. As a treatment for a rare disease in children, Orphion's Pediatric Therapeutic was eligible for the Rare Pediatric Disease Priority Review Voucher Program operated by the FDA. The program aims to incentivize drug development for rare pediatric diseases—which otherwise might be unprofitable or too risky to develop—by offering to any company who receives an approval for a therapeutic of rare pediatric disease, a voucher that can be redeemed to receive priority review for a different product (a "PRV"). Because a PRV can transferred or sold to any

other pharmaceutical company, they are immensely valuable—worth at least $100 million in the open market.

30. If not for Defendants' conduct in breaching or causing the breach of the Agreements, Orphion would have gotten its Pediatric Therapeutic designated by the FDA as a treatment for a rare pediatric disease and, upon approval of the treatment, would have earned a PRV.

31. In addition to the PRV, successfully bringing Orphion's Pediatric Therapeutic to market would have conservatively earned Orphion over $500 million in revenue in only the first five years of sales. But, as explained below, the viability of Orphion's Pediatric Therapeutic and Orphion's value was destroyed by Defendants for their own greed.

Orphion Purchases Exclusive Licensing Rights and Vector Materials from CHOP in Order to Develop its Pediatric Therapeutic

32. In order to develop Orphion's Pediatric Therapeutic, Orphion required certain CHOP intellectual property rights related to TPP1 and other gene therapies, and the cGMP Vector Materials for use in clinical trials.

33. CHOP was in possession of such materials, which were manufactured by Davidson and/or her team using CHOP's facilities in late 2018.

34. Orphion representatives held discussions with CHOP representatives throughout 2018 and early 2019, including both telephone calls and in-person meetings to examine whether Orphion could utilize certain of CHOP's intellectual property related to TPP1 and other gene therapies as part of Orphion's efforts to develop Orphion's Pediatric Therapeutic, including an IND or foreign equivalent application for clinical trials and eventually regulatory approvals.

35. From the earliest stages of the negotiation process, Defendants were aware that Orphion was based in New York, and directed communications to Orphion in New York. In fact,

on numerous occasions, Defendants called and sent letters to Orphion and its representatives in New York.

36. These discussions culminated in a signed term sheet on or about April 5, 2019. The Term sheet was not binding but laid out the basic terms of agreement between the parties and created a 150-day period where Orphion would have the exclusive right to negotiate a definitive agreement. Orphion and CHOP then continued negotiations, which led to the execution of the License Agreement with an effective date of October 28, 2019. Zev Sunleaf ("Sunleaf"), the Vice President of Technology Transfer, Commercialization, and Research Contracts for CHOP, signed both the term sheet and the License Agreement on behalf of CHOP, acting as CHOP's authorized official. A true and correct copy of the License Agreement and an amendment entered on May 5, 2020 to defer certain costs and milestones due are attached hereto as Exhibit 1.

37. Pursuant to Sections 2.13 and 3.1 of the License Agreement, as well as Appendices A and E, CHOP granted Orphion exclusive rights "to make and have made, to use and have used, to offer for sale and have offered for sale, to sell and have sold, and to import and have imported" various patents and patent applications owned by CHOP for "Gene Transfer Composition, Methods and Uses for Treating Neurodegenerative Diseases" as well as co-owned intellectual property titled "Methods and Vectors for Treating CNS Disorders" co-owned by CHOP and Spark Therapeutics, and any products resulting from those patents. As described in License Agreement Section 2.22, the subjects of these patents and patent applications "were created in the course of research at CHOP by Beverly Davidson" and others.

38. Under License Agreement Section 13.1, the License Agreement was "effective as of the Effective Date and shall extend until the expiration of the Royalty Term unless sooner terminated as provided in this Article 13." The Effective Date is October 28, 2019 and the Royalty

Term is, per Section 2.20, "the period beginning on the Effective Date and ending on the later to occur of (a) the expiration, invalidation or abandonment of the last Licensed Patent Rights or CHOP Co-Owned IP or (b) ten (10) years from the First Commercial Sale," where the First Commercial Sale refers to, pursuant to License Agreement Section 2.6, "the initial transfer … of Licensed Product or the initial rendering of services under a Licensed Process by or on behalf of Licensee or its sublicenses in exchange for cash or some equivalent to which value can be assigned for the purpose of determining Net Sales." At no point did any of the express, enumerated termination-inducing events occur.

39. The License Agreement also gave Orphion "an exclusive option … to negotiate (a) an exclusive, worldwide, transferable, sublicensable license to any and all Future CHOP IP." (Ex. 1, § 3.3.) Future CHOP IP is defined as "all discoveries and inventions that constitute patentable advancements, developments, or improvements" to CHOP's patents and applications, including "Methods and Vectors for Treating CNS Disorders" and "Methods and Uses for Treating Neurodegenerative Diseases." (*Id.* §§ 2.8, 2.22.)

40. As originally contemplated, the License Agreement (which provided Orphion the exclusive right to utilize certain of CHOP's intellectual property including the Vector Materials) would include Orphion's acquisition of the cGMP Vector Materials. However, on July 2, 2019, during discussions related to the License Agreement, CHOP notified Orphion that the purchase of the cGMP Vector Materials should be removed from the License Agreement, and, instead, that a separate agreement should be entered into related to the cGMP Vector Materials.

41. However, it was understood at all times by Orphion, CHOP, Davidson, and Sunleaf that Orphion would need to purchase the cGMP Vector Materials in order to conduct its clinical trials and reach the milestones described in the License Agreement. Indeed, the License

Agreement expressly references "materials transferred by or on behalf of CHOP to Licensee to research." (Ex. 1 §3.2.) Similarly, in Section 15.8 of the License Agreement, Orphion agreed that "its use of any CHOP supplied materials" would "comply with all applicable statutes, regulations, and guidelines." And Orphion agreed "not to use the materials for research involving human subjects or clinical trials" unless it complied "with 21 C.F.R. § Part 50 and 45 C.F.R. § Part 46" and notified CHOP first. (*Id.* §15.8.)

42. The parties engaged in further discussions and negotiations relating to the Purchase Agreement. Those negotiations started in or around December 2019 and included various communications among the parties exchanging draft agreements. Thus, the Purchase Agreement would not have been entered into but-for the primary License Agreement and CHOP's insistence on the matter. Therefore, CHOP cannot—in good faith and fair dealing—use its own breach of the Purchase Agreement as a basis for terminating the Licensing Agreement.

43. The Purchase Agreement was finally executed on September 11, 2020. Sunleaf signed the Purchase Agreement on behalf of CHOP, acting as CHOP's authorized official, a copy of which is attached hereto as Exhibit 2. Another company founded by Davidson, Spark Therapeutics, Inc., also signed off on the sale of the Vector Materials to Orphion. (*Id.* at signature page.)

44. Under the Purchase Agreement, Orphion purchased CHOP's already-manufactured cGMP Vector Materials in exchange for $682,189 to be paid out over time. Section 1.1 of the Purchase Agreement explicitly provided that "CHOP hereby sells, assigns, transfers, and conveys to [Orphion], and [Orphion] hereby acquires, accepts and purchases from CHOP, ***all of CHOP's right, title and interest*** in the [cGMP Vector Materials]." (*Id.* §1.1.)

45. The cGMP Vector Materials were identified in Schedule 1 of the Purchase Agreement as: (i) HEK293 master/working cell bank; (ii) plasmids for tri-transfection; (iii) raw materials used in working cell bank production; (iv) reagents, solvents, and auxiliary materials used in the manufacture of AAV2-CAG-TPP1; (v) buffers used in the manufacture of AAV2-CAG-TPP1; (vi) letter of authorization for the FDA to review the Lot release file and access to the Lot release file for review during the GMP audit; and (vii) AAV2-CAG-TPP1, Lot A2FP1-A1804C-C. (Ex. 2, Schedule 1.) Exhibit A to Schedule 1 provided a description of AAV2-CAG-TPP1, Lot A2FP1-A1804C-C, also known as "Viral vector SPK-1002," as having been "manufactured in compliance with current Good Manufacturing Practices ("cGMP") for "early phase clinical trials," and consisting of "416 vials" at 0.25 ml per vial. (*Id.*, Schedule 1, Ex. A.)

46. As explained in the third Whereas clause of the Purchase Agreement, "the purchase of the Material is **necessary** for Customer to perform IND-enabling activities as well as clinical trials for certain rare and orphan diseases, as well as for clinical development and commercial activities relating to use of the Material for treatment of such diseases." (*Id.* at pg. 1 (emphasis added).) Thus, CHOP was certainly aware that Orphion needed the 416 vials of cGMP Vector Materials in order to conduct the IND and clinical trials and create Orphion's Pediatric Therapeutic.

47. Under the Purchase Agreement, CHOP would store the Vector Materials in their specialized freezer until Orphion "requests shipment to a single location to be later specified." (*Id.* §3.1.) "Delivery of the entire lot of Material designated for human use may be requested by the Customer at any time during the Term of this Agreement." (*Id.*) Although CHOP could charge "storage fees" if it was required to store the Vector Materials for more than six months, CHOP never did so.

48. Orphion made the initial payment of $68,219 as contemplated in Schedule 3 of the Purchase Agreement on or about October 27, 2020. Additional payments were to be made when the Materials passed certain testing milestones. (*Id.*, Schedule 3.).

49. Neither the License Agreement nor the Purchase Agreement contained any terms allowing CHOP to unilaterally use-up, sell, or otherwise make unavailable the cGMP Vector Materials purchased by Orphion. And CHOP was certainly not permitted to provide or promise the Vector Materials to a competitor—or use them to create such a competitor—which would breach both Agreements.

50. Prior to conducting human clinical studies, Orphion was required to conduct non-clinical studies with monkeys. Unlike the human clinical studies which required cGMP Vector Materials, the non-clinical studies could be conducted with non cGMP AAV2-TPP1 bulk drug substance (the "non-cGMP Material"). Orphion also purchased non-cGMP Material from CHOP that was also stored in CHOP's facilities.

51. Orphion paid CHOP $167,492 in exchange for the non-cGMP Material.

Orphion Continues its Critical Research While CHOP Affirms and Reaffirms its Obligation and Intent to Store Orphion's cGMP Vector Materials

52. Upon entering into the Agreements with CHOP, Orphion remained steadfastly committed to its goals and obligations, investing significant time, energy, and resources to move forward with the development of Orphion's Pediatric Therapeutic as well as secure additional funding for preclinical development and clinical trials.

53. Orphion provided periodic updates to CHOP about the development of Orphion's Pediatric Therapeutic. For example, on or about September 14, 2021, Orphion provided CHOP a report titled "Orphion Therapeutics, Inc. Progress Report on CHOP Licensed Assets." This progress report included in relevant part that Phase 1 clinical trials were intended to be initiated

"by end of Q1 2022." CHOP accepted the September 14, 2021 progress report without any comments, objections, or request to amend the License Agreement or the Purchase Agreement.

54. As of September 14, 2021, neither Sunleaf, nor Davidson, nor anyone else from CHOP indicated that there was any issue with the availability of the cGMP Vector Materials that could affect the viability of Orphion's commercial plan under the License Agreement.

55. In or around October 2021, Orphion finalized its Phase 1 trial synopsis for FDA review.

56. Although CHOP was required to provide the supporting data under the Agreements, Orphion discovered that CHOP did not have the required documentation of the data. CHOP had not followed standard practices for preparing protocols in advance of animal experiments, and had not properly managed the data or done the assay work required.

57. Therefore, Orphion determined it would have to review and create all necessary documentation for regulatory filings, despite having paid CHOP for this exact documentation. Because it fell to Orphion to do substantial work that should have been done by CHOP, it slowed down the process for submitting the regulatory application to begin clinical trials.

58. Orphion was also forced to pay tens of thousands of dollars to audit the quality of cGMP Vector Materials—necessary for approval of use of the Vector Materials in clinical studies—despite the Purchase Agreement requiring CHOP to provide such information and supporting documents.

59. In January of 2022, while Orphion was working on getting approval for the use of the Vector Materials, Orphion's CEO, Dr. Jason Slakter ("Dr. Slakter"), emailed CHOP's Director of Clinical Vector Core, Johannes Van der Loo ("Van der Loo"), writing "I just want to make sure

that the GMP material will continue to be stored as required and available …" Van der Loo responded: "Confirming that we will maintain the material in GMP storage …"

60. Six months later, on July 29, 2022, a member of CHOP's Clinical Vector Core team contacted Dr. Slakter inquiring whether Orphion planned to treat patients in 2023 (thus requiring use of the cGMP Vector Materials). Dr. Slakter confirmed Orphion's plans to do so, noting that "no subjects will be enrolled in 2022. For 2023, the numbers remain the same at 6-9 subjects expected to be enrolled." Dr. Slakter included in that email its Phase 1 trial synopsis. In other words, by this time, and on multiple occasions well before, CHOP was on notice that Orphion would require the cGMP Vector Materials in 2023.

61. In response, CHOP provided no indication that CHOP had any problem or dispute with this timeline. Nor did CHOP inform Dr. Slakter that the cGMP Vector Materials might no longer be available at that time.

In 2023, CHOP Falsely Claims that CHOP No Longer Has the cGMP Vector Materials and Then Terminates the Licensing Agreement and Purchase Agreement in Bad Faith

62. By February 2023, Orphion had identified a lead study site and a pediatric patient population with high, unmet medical need that would benefit from treatment with Orphion's Pediatric Therapeutic. Orphion also completed studies that were prerequisites to filing a regulatory application in Canada, and planned to begin the Phase 1 clinical trials in the coming months.

63. On April 18, 2023, Sunleaf asked Dr. Slakter, via email "[c]ould you let me know the exact number of VGs [vials] you will need-or the number of vials at a given titer of x vg/mL for this first tranche, and then over time?" As CHOP and Davidson were aware, Orphion had purchased and had a contractual right to demand delivery of all 416 vials of the cGMP Vector Materials pursuant to the License Agreement and Purchase Agreement. Time and again over the preceding years, Orphion represented that it intended to use all 416 vials.

64. On the same day, Dr. Slakter replied to Sunleaf that Orphion would need 90 vials within the next month or so, but would need the full 416 vials shortly thereafter in preparation for the clinical trials. Again, Sunleaf did not inform Orphion that there was any reason CHOP would not be able to deliver all 416 vials of the cGMP Vector Materials.

65. In a sudden about-face, on June 1, 2023, Sunleaf emailed Dr. Slakter to inform him *for the first time* that the cGMP Vector Materials Orphion had purchased were no longer available. Sunleaf wrote "I also wanted to make you aware that we only have 125 vials of clinical TPP1 … We no longer have the 400 vials from 3 years ago." On information and belief, this was a lie. CHOP still had the 416 vials of cGMP Vector Materials but had decided to sell all or most of them to Latus—or Davidson had already taken and used the vials for Latus.

66. Dr. Slakter was shocked by this claim from Sunleaf that CHOP no longer had the full lot of cGMP Vector Materials. As Orphion had repeatedly told CHOP, all 416 vials were necessary for Orphion to conduct clinical trials. And CHOP had assured Orphion that it would continue to store the cGMP Vector Materials.

67. Dr. Slakter immediately replied to Sunleaf, writing that that he was "shocked to learn that the 400 vials of material [were] no longer available. We have been actively working and incurring costs to move the program forward based on the agreement to purchase this material." That same day, Dr. Slakter further responded requesting conference call on the issue as soon as possible and attached prior emails in which Orphion and CHOP had reiterated Orphion's need and CHOP's obligation to store all of the cGMP Vector Materials "for our use with plans for clinical trials in 2023. At no time did we receive any further communication from the Vector Core around this material nor did we provide any instructions for them to destroy or divert this material."

68. Sunleaf responded that he was "reaching out to few people internally to see who else should be on the call." Despite repeated requests from Orphion, Sunleaf and CHOP never set up the call. Because CHOP refused to participate in a call, Orphion was never able to determine whether the remaining vials were the cGMP Vector Materials or the non-cGMP Materials.

69. Instead, on June 8, 2023—a week after informing Orphion that CHOP could not deliver the purchased cGMP Vector Materials—CHOP sent Orphion a letter purporting to terminate the License Agreement (the "June 8 Letter"). A copy of the June 8 Letter is attached hereto as Exhibit 3. The one-page letter, signed by Sunleaf, attempted to enumerate breaches of various terms of the License Agreement. This "notice of breach" and termination was a bogus attempt by Defendants to deflect from their gross breach of the Purchase Agreement.

70. Indeed, prior to sending the June 8 Letter, CHOP had never indicated any warning or intent about terminating the License Agreement—with the exception of the "MPS III" IP program, which CHOP requested to amend out of the License Agreement on June 1, 2023 and which is not related to CLN2 or Orphion's Pediatric Therapeutic. On the contrary, on June 1, 2023, Sunleaf wrote to Orphion that CHOP did not want to terminate the License Agreement but merely to amend it to remove the MPS III program.

71. The "breaches" listed in the June 8 Letter are plainly not a valid basis for termination. Two of the purported breaches are for not paying invoices under §7.5 and §7.6 of the License Agreement. But there were no outstanding invoices under §7.6 and although there were some outstanding invoices under §7.5, the total was well under $100,000 and CHOP knew that Orphion had just received interim financing which would easily allow them to pay those bills. This was certainly not a material breach.

72. The next two purported "breaches" were for failing "to bring the licensed products to practical application" and the performance of certain milestones which were made impossible to remedy by CHOP refusing to deliver the cGMP Vector Materials necessary to start clinical trials on Orphion's Pediatric Therapeutic. Thus, CHOP was using its own breach of the Purchase Agreement as a basis for terminating the License Agreement.[1]

73. On June 14, 2023, in response to CHOP's notice of termination of the License Agreement, Orphion's counsel sent a letter to Sunleaf and CHOP demanding information related to the cGMP Vector Materials and identifying some of Defendants' bad faith actions. The letter demanded that CHOP provide comprehensive information related to the missing vials of cGMP Vector Materials. A copy of Orphion's June 14, 2023 demand letter is attached hereto as Exhibit 4. CHOP never responded to Orphion's demand letter.

74. Instead, on August 16, 2023, CHOP sent a letter to Orphion purporting to "terminate the Vector Purchase Agreement" effective September 17, 2023. The Purchase Agreement does not contain a termination provision. Additionally, CHOP's purported grounds for terminating the Purchase Agreement was Orphion's failure to fully pay for the cGMP Vector Materials that CHOP had previously told Orphion it no longer had and certainly never delivered. In other words, in a clear effort to try to bully a small start-up company into simply going away, Defendants were claiming the ability to terminate an agreement that (i) had no termination provisions and (2) that they had breached since they admitted they would not supply the cGMP Vector Materials.

[1] The last breach was for failing to hit certain milestones on the MPS III Program. As previously noted, CHOP had already requested amending—not terminating—the Licensing Agreement to remove this program and Orphion did not disagree.

75. CHOP's June 8 and August 16 letters also try to create a false narrative of CHOP being the victim. On the contrary, Orphion worked hand-in-hand with CHOP to bring its Pediatric Therapeutic to clinical trials. Orphion spent tens of thousands of dollars doing work that CHOP should have done and redoing work that CHOP did poorly and over $5 million developing its Pediatric Therapeutic. Orphion continually kept CHOP abreast of all developments, delays, issues, and progress. Indeed, CHOP knew in mid-2022 that the earliest clinical trials would take place was in 2023 and that Orphion would require the cGMP Vector Materials to conduct them. Yet CHOP did not purport to find breaches in the Agreements until a year later, when Orphion tried to hold CHOP to their obligation to deliver the Vector Materials that Orphion had purchased.

76. Orphion was shocked and confounded by CHOP's conduct. Without the cGMP Vector Materials and the Licensed Patent Rights, Orphion could not move forward with the regulatory application to begin a clinical trial for its promising Orphion's Pediatric Therapeutic. CHOP had breached the Agreements for no apparent reason knowing it would result in Orphion closing its operations and preventing Orphion's Pediatric Therapeutic from reaching the market—thus condemning more children suffering from CLN2 to blindness.

The Truth is Revealed When Davidson Founds Latus and Publicly Announces its Plan to Create its own CLN2 Treatment.

77. The mystery of CHOP's refusal to deliver all 416 vials of cGMP Vector Materials was finally revealed in May of 2024 when a new company—Latus—co-founded by Davidson, announced that it had raised $54 million and planned clinical trials for the treatment of CLN2. *See* Kyle LaHucik, *Exclusive: Spark co-Founder Launches New CNS Gene Therapy Biotech with $54M*, Endpoint News (May 2, 2024 6:30 AM), https://endpts.com/spark-co-founder-launches-new-cns-gene-therapy-startup-latus-bio-with-54m/.

78. Davidson, together with venture capitalists, had created Latus as LastAAV, Inc. on May 2, 2022. On February 13, 2023, LastAAV, Inc. changed its name to Latus Bio.

79. Davidson, as the Chief Scientific and Strategy Officer at CHOP's Research Institute and leader of the Clinical Vector Core at CHOP, and her team at CHOP received regular updates from Orphion about their idea to treat CLN2 blindness with Orphion's Pediatric Therapeutic—using patents developed by Davidson and exclusively licensed from CHOP.

80. On information and belief, Davidson and Latus decided to take Orphion's Licensed Patent Rights and create their own pediatric therapeutic for CLN2. And, in order for Latus to develop a pediatric therapeutic for CLN2, they needed to work with the cGMP Vector Materials and use the Licensed Patent Rights. Unfortunately for Latus, CHOP had sold the Vector Materials and Licensed the Patent Rights to Orphion.

81. On information and belief, in 2022 or early 2023, Davidson and Latus approached CHOP and requested to use—or simply took, in Davidson's capacity as leader of CHOP's Clinical Vector Core—some or all of the vials of the cGMP Vector Materials despite knowing it would require CHOP breaching the Purchase Agreement and result in the destruction of Orphion's business.

82. At first, CHOP tried to have their cake and eat it too. They let Davidson and Latus take the cGMP Vector Materials Orphion they wanted and tried to pacify Orphion with fewer vials or non-cGMP Materials. But after Orphion demanded all the vials it had purchased under the Purchase Agreement, CHOP decided to breach both Agreements and give all the cGMP Vector Materials and the Licensed Patent Rights to Latus.

83. Sunleaf and CHOP also lied to Orphion in claiming that CHOP no longer had the cGMP Vector Materials. CHOP still had the cGMP Vector Materials, they just decided to give them to—or use them for—Latus instead of Orphion.

84. CHOP benefited from breaching its Agreements with Orphion and contracting with Latus, and Latus and Davidson benefitted from being able to use the cGMP Vector Materials and the Licensed Patent Rights that properly belonged to Orphion. Additionally, Latus offered CHOP an opportunity to become a syndicate investor in Latus. CHOP took Latus' offer and destroyed Orphion as a viable business.

85. Moreover, because Latus is focusing on treatment of the general loss of motor and intellectual function in children with CLN2—for which an FDA-approved treatment already exists—Latus and CHOP have prevented the creation of a treatment to prevent blindness in children suffering from CLN2. How many children will go blind because of Latus and CHOP's greed?

Davidson and Latus Use Orphion's Confidential Reports and Data

86. Starting in 2019, after Orphion executed the Licensing Agreement, Orphion did significant work on the Vector Materials and the Patent License Rights. Orphion regularly shared the results of its work on CLN2 treatment and AAV-TPP1 with CHOP and Davidson.

87. For example, for a significant portion of time during the Term of the License Agreement, Orphion representatives conducted weekly meetings with a team from CHOP regarding preclinical work on the use of the Vector Materials in animal studies and in the preparation of materials to meet regulatory requirements.

88. Similarly, in 2019 and 2020, Orphion representatives, the CHOP team, and the University of Hamburg held regular teleconferences to discuss clinical development plans.

89. Orphion also provided CHOP with confidential decks, marked as such, with the results of studies conducted by Orphion on the effectiveness of delivery of the AAV-TPP1, plans for conducting clinical trials and revenue modeling for Orphion's Pediatric Therapeutic.

90. Finally, Orphion had regular email correspondence with CHOP discussing Orphion's ideas for auditing and using the cGMP Vector Materials in a manner that would gain regulatory acceptance.

91. All of this data and information were highly confidential trade secrets that Orphion developed at great cost and provided to CHOP pursuant to the Licensing Agreement. (*See, e.g.* Ex. 1 §§9.2, 9.9.) The Licensing Agreement specifically prohibited either party from disclosing or using "Confidential Information" received from the other party during the life of the Licensing Agreement and three years after its expiration or termination. (*Id.* at § 14.1.)

92. Nevertheless, on information and belief, Davidson and CHOP breached the License Agreement by sharing Orphion's Confidential Information with Latus. For example, in a recent lecture, Davidson described how her most recent vector AAV-Ep+, worked better than the type of Vector Materials Orphion purchased, AAV2-TPP1 in non-clinical studies—something Davidson could only claim using Orphion's Licensed Patent Rights, Vector Materials, and confidential data from its non-clinical study with the non-cGMP Vector Materials. Davidson developed the AAV-Ep+ vector in her work in CHOP's Research Institute and Clinical Vector Core program.

93. Moreover, because Davidson and Latus are claiming their CLN2 treatment method is an advancement or improvement on the type of AAV2-TPP1 that Orphion exclusively licensed from CHOP, under the License Agreement, Latus' AAV-Ep+ technology is "Future CHOP IP" and Orphion was entitled to negotiate an exclusive license to this technology. (Ex. 1, §§ 2.8, 3.3.) Instead, CHOP has breached and purported to terminate the Agreements and Latus has taken

Orphion's Vector Materials, Licensed Patent Rights—including the Future CHOP IP—and confidential trade secrets to benefit themselves and destroy Orphion.

CAUSES OF ACTION

FIRST CAUSE OF ACTION
(Breach of Contract – Against CHOP)

94. Orphion incorporates by reference the allegations in the above paragraphs.

95. Orphion and CHOP entered into a License Agreement in 2019 that granted Orphion exclusive Licensed Patent Rights necessary for Orphion to develop its Pediatric Therapeutic.

96. In 2020 Orphion and CHOP entered into the Purchase Agreement in which Orphion purchased, among other items, 416 vials of cGMP Vector Materials. Under the Purchase Agreement, CHOP agreed to store the cGMP Vector Materials until Orphion requested delivery.

97. Orphion diligently worked with CHOP to perform all of its duties under the License Agreement from 2019 through 2023, including providing CHOP with regular updates of Orphion's progress and reports of Orphion's findings.

98. On June 1, 2023, CHOP told Orphion that it no longer had the 416 vials of cGMP Vector Material that Orphion had purchased and would not be delivering them as requested by Orphion. CHOP thereby breached the Purchase Agreement. But this was false. CHOP still had the vials but wanted to provide them to Orphion's competitor, Latus, or had already done so.

99. On information and belief, CHOP knew that it would be providing the vials to Latus and breaching the Purchase Agreement since at least February of 2023. Despite this knowledge, CHOP strung Orphion along for months and continued to accepted payments from Orphion and send bills to Orphion under the License Agreement.

100. The cGMP Vector Materials were necessary for Orphion to conduct clinical trials for its Pediatric Therapeutic. CHOP's breach of the Purchase Agreement, therefore, made it impossible for Orphion to continue to operate as a viable business.

101. Orphion immediately demanded an explanation for the breach and a conference call with CHOP personnel to discuss ways to potentially mitigate the breach. CHOP responded on June 8, 2023 by purporting to terminate the License Agreement, in part on the grounds that Orphion would not be able to bring its Pediatric Therapeutic to clinical trials—which CHOP itself had caused by breaching the Purchase Agreement.

102. This termination was not valid under any terms of the License Agreement and, therefore, CHOP's refusal to perform its obligations was a breach of the License Agreement. CHOP then provided Orphion's Licensed Patent Rights to Latus, further breaching the License Agreement.

103. CHOP's breach of the Agreements was willful misconduct and included knowing fraud and a bad faith termination. CHOP, therefore, is liable for the consequential damages to Orphion by CHOP's breaches of the Agreements.

104. As a result of CHOP's breaches of the Agreements, Orphion had to cease operations and was damaged in the amount of its full value, at least $27.2 million as of 2019. Moreover, Orphion lost its opportunity to earn a PRV worth at least $100 million and future revenue in excess of $500 million.

SECOND CAUSE OF ACTION
(Breach of the Confidentiality Provisions of the License Agreement – Against CHOP and Davidson)

105. Orphion incorporates by reference the allegations in the above paragraphs.

106. Orphion and CHOP entered into a License Agreement in 2019 that granted Orphion exclusive Licensed Patent Rights necessary for Orphion to develop its Pediatric Therapeutic.

107. Section 9.9 of the License Agreement provided that "[a]ll plans and reports" that Orphion was required to provide CHOP and "marked confidential by [Orphion] shall, to the extent permitted by law, treated by CHOP as … privileged and confidential." (Ex. 1 § 9.9.)

108. Section 14.1 of the License Agreement provided that for the term of the License Agreement and "three (3) years after the earlier of the expiration or termination of this Agreement" CHOP was prohibited from disclosing any "Confidential Information" received from Orphion without prior written consent. (*Id.* § 14.1.) "Confidential Information" is, in turn, defined to mean "any proprietary or confidential information, technical data, Know-How, research, product plans, developments, inventions, processes, protocols, formulas, marketing plans, strategies, customer lists, and other information or material that are disclosed or provided by a Party to the other Party." (*Id.* § 2.5.)

109. Orphion spent over $5 million in developing the preclinical work, clinical development plans, audit of the cGMP Materials, discussions with the FDA and Canadian regulatory authorities, and conducting non-clinical studies.

110. Pursuant to the License Agreement, Orphion provided CHOP and Davidson with confidential reports and data on work that Orphion did in connection with the development of its Pediatric Therapeutic, including regular meetings or teleconferences regarding preclinical work and clinical development plans, audits and ancillary work on the quality and usability of the cGMP Vector Materials to satisfy regulatory authorities, and the results of non-clinical studies conducted by Orphion.

111. Davidson received Orphion's confidential reports and data in her capacity as the Chief Scientific and Strategy Officer of CHOP's Clinical Vector Core. Davidson was thus obligated to keep Orphion's confidential reports and data confidential under the License Agreement. Instead, she and CHOP breached Sections 9.9 and 14.1 of the License Agreement (the "Confidentiality Provisions"), shared Orphion's confidential reports and data with Latus and used Orphion's confidential reports and data in developing Latus' CLN2 treatment—including to measure and improve the effectiveness of their own CLN2 treatment.

112. As a result of CHOP's breach of the Confidentiality Provisions, Orphion has been damaged in an amount to be determined at trial, but not less than the over $5 million Orphion spent in developing its confidential information, plus the profits lost by Orphion and gained by CHOP and Davidson from sharing Orphion's confidential reports and data with Latus.

THIRD CAUSE OF ACTION
(Breach of the Implied Covenant of Good Faith and Fair Dealing – Against CHOP)

113. Orphion incorporates by reference the allegations in the above paragraphs.

114. Orphion and CHOP entered into a License Agreement in 2019 that granted Orphion exclusive Licensed Patent Rights necessary for Orphion to develop its Pediatric Therapeutic.

115. Under the License Agreement, Orphion was permitted to amend the milestones and any time periods in the Orphion's "Commercial Development Plan" on consent by CHOP which would "not be unreasonably withheld, conditioned, or delayed." (Ex. 1 §9.2).

116. Every contract includes an implied covenant of good faith and fair dealing that a party will not act in a manner that would deprive the other party of the right to receive the benefits they had bargained for in the agreement.

117. In 2020 Orphion and CHOP entered into the Purchase Agreement in which Orphion purchased, among other items, 416 vials of cGMP Vector Materials. Under the Purchase Agreement, CHOP agreed to store the cGMP Vector Materials until Orphion requested delivery.

118. On June 1, 2023, CHOP informed Orphion that it would not be delivering the 416 vials of cGMP Vector Materials that Orphion had purchased.

119. On information and belief, CHOP knew that it would be providing the vials to Latus and breaching the Purchase Agreement since at least February of 2023. Despite this knowledge, CHOP strung Orphion along for months and continued to accepted payments from Orphion and send bills to Orphion under the License Agreement.

120. The cGMP Vector Materials were necessary for Orphion to conduct clinical trials for its Pediatric Therapeutic. CHOP's breach of the Purchase Agreement, therefore, made it impossible for Orphion to continue to operate as a viable business.

121. Orphion immediately demanded an explanation for the breach and a conference call with CHOP personnel to discuss ways to potentially mitigate the breach. CHOP responded on June 8, 2023 by purporting to terminate the License Agreement, in part on the grounds that Orphion would not be able to bring its Pediatric Therapeutic to clinical trials—which CHOP itself had caused by breaching the Purchase Agreement.

122. To the extent CHOP's termination was permissible under the terms of the License Agreement it breached the implied covenant of good faith and fair dealing because (i) CHOP itself caused the purported grounds for termination when it breached the Purchase Agreement; and (ii) CHOP unreasonably, and without warning, refused to work with Orphion to amend to milestones and time periods in the Licensing Agreement.

123. As a result of CHOP's bad faith termination of the License Agreement, Orphion had to cease operations and was damaged in the amount of its full value, at least $27.2 million as of 2019. Moreover, Orphion lost its opportunity to earn a PRV worth at least $100 million and future revenue in excess of $500 million.

FOURTH CAUSE OF ACTION
(Fraud – Against CHOP)

124. Orphion incorporates by reference the allegations in the above paragraphs.

125. In 2020 Orphion and CHOP entered into the Purchase Agreement in which Orphion purchased, among other items, 416 vials of cGMP Vector Materials. Under the Purchase Agreement, CHOP agreed to store the cGMP Vector Materials until Orphion requested delivery.

126. In 2022, in multiple communications, CHOP representatives assured Orphion that it was still had and was storing the cGMP Vector Materials. Orphion, in turn, informed CHOP that it would need the materials in 2023 to begin clinical trials.

127. In April of 2023, Sunleaf asked Orphion how many of the 416 vials they would need, in the short term and long term. Orphion answered that it would need 90 vials in the next month or so but would need all 416 vials shortly thereafter. Sunleaf did not respond. On information and belief, at that time, CHOP had already provided, or already knew that they would be providing, most or all of the vials of cGMP Vector Materials to Davidson for Latus' use. CHOP's silence about the true availability of the 416 vials was a material omission of fact, made for the purpose of keeping Orphion relying on the Purchase Agreement and continuing to do business with and pay CHOP.

128. Between April 2023 and June 2023, Orphion continued to rely on CHOP storing the 416 vials of cGMP Vector Materials.

129. Then, on June 1, 2023, Sunleaf—on behalf of CHOP—told Orphion that it no longer had all 416 vials. On information and belief, this was false. In reality CHOP still had all 416 vials but wanted to give most or all of them to Latus, or had already given most of them to Latus. Instead CHOP made it seem like the vials had gone bad and were no longer physically available or useable.

130. With this false representation, CHOP and Sunleaf intended to keep Orphion under contract and paying under the Agreements while also investing and profiting from Latus' use of the Vector Materials.

131. Although Orphion protested CHOP's declaration that it no longer had the 416 vials as a breach of the Purchase Agreement, Orphion believed Sunleaf's claim that the vials no longer existed and did not bring an action for specific performance.

132. As a result of CHOP's deceptions, Orphion had to cease operations and was damaged in the amount of its full value, at least $27.2 million as of 2019. Moreover, Orphion lost its opportunity to earn a PRV worth at least $100 million and future revenue in excess of $500 million.

FIFTH CAUSE OF ACTION
(Tortious Interference with Contract– Against Latus and Davidson)

133. Orphion incorporates by reference the allegations in the above paragraphs.

134. Orphion and CHOP entered into a License Agreement in 2019 that granted Orphion exclusive Licensed Patent Rights necessary for Orphion to develop its Pediatric Therapeutic.

135. In 2020 Orphion and CHOP entered into the Purchase Agreement in which Orphion purchased, among other items, 416 vials of cGMP Vector Materials. Under the Purchase Agreement, CHOP agreed to store the cGMP Vector Materials until Orphion requested delivery.

136. Davidson, a founder of Latus, communicated with Orphion's CEO about the Vector Materials and the Licensed Patent Rights and was fully aware of the existence of the Agreements. Davidson and her team at CHOP also regularly communicated with Orphion in connection with the Licensed Patent Rights and Orphion's Pediatric Therapeutic.

137. In addition to Davidson, other members of CHOP's Clinical Vector Core team routinely interacted with Orphion pursuant to the License Agreement and billed Orphion for services under that agreement.

138. Davidson and other members of CHOP's Clinical Vector Core formed Latus in May of 2022. Davidson and Latus, therefore, knew about the existence of the Agreements and CHOP's obligations thereunder.

139. At some point in 2022 or the first half of 2023, Davidson and Latus decided to use the cGMP Vector Materials that were sold to Orphion. On information and belief, Davidson and Latus either convinced CHOP to breach the Purchase Agreement or Davidson directly caused CHOP to breach the Purchase Agreement in her capacity within CHOP.

140. Then, when Orphion protested the breach of the Purchase Agreement in June of 2023, Davidson and Latus convinced or directed CHOP to breach the License Agreement as well by terminating it on invalid grounds.

141. As a result of Latus and Davidson's tortious interference with the Agreements, Orphion had to cease operations and was damaged in the amount of its full value, at least $27.2 million as of 2019. Moreover, Orphion lost its opportunity to earn a PRV worth at least $100 million and future revenue in excess of $500 million.

SIXTH CAUSE OF ACTION
(Conversion – Against Latus and CHOP)

142. Orphion incorporates by reference the allegations in the above paragraphs.

143. In 2020 Orphion and CHOP entered into the Purchase Agreement in which Orphion purchased, among other items, 416 vials of cGMP Vector Materials. Under the Purchase Agreement, CHOP agreed to store the cGMP Vector Materials until Orphion requested delivery.

144. But from the execution of the Purchase Agreement, CHOP sold and Orphion acquired "all of CHOP's right, title and interest in the [cGMP Vector Materials]." (Ex. 2 at §1.1.)

145. Therefore, from the time of the execution of the Purchase Agreement, Orphion had legal ownership of the cGMP Vector Materials.

146. CHOP agreed to store the cGMP Vector Materials, but Orphion had the right to request "Delivery of the entire lot of Material … at any time during Term of this Agreement. (*Id.* §3.1.) Thus, Orphion had an immediate right of possession of the cGMP Vector Materials.

147. At some point in 2022 or 2023, CHOP—without Orphion's authorization—took some, and then all, of the cGMP Vector Materials and gave them to Latus or used them on behalf of Latus.

148. Latus has since used the cGMP Vector Materials to begin development of its own CLN2 therapeutic. Latus has raised at least $54 million to fund its planned CLN2 therapeutic on the back of the cGMP Vector Materials it stole from Orphion. And Latus expects to make substantial profits from its CLN2 therapeutic.

149. As a result of CHOP and Latus' conversion of Orphion's cGMP Vector Materials Orphion has lost the expected profits of its own Pediatric Therapeutic, in an amount to be determined at trial, but not less than $100 million for the PRV and profits on expected revenue of over $500 million in just the first five years of sales.

SEVENTH CAUSE OF ACTION
(Common Law Misappropriation of Trade Secrets – Against Latus and Davidson)

150. Orphion incorporates by reference the allegations in the above paragraphs.

151. Pursuant to the License Agreement, Orphion acquired the exclusive Licensed Patent Rights from CHOP.

152. Also pursuant to the License Agreement, Orphion provided CHOP and Davidson with confidential reports and data on work that Orphion did in connection with the development of its Pediatric Therapeutic, including regular meetings or teleconferences regarding preclinical work and clinical development plans, audits and ancillary work on the quality and usability of the cGMP Vector Materials, and decks with the results of studies conducted by Orphion.

153. Under Sections 9.9 and 14.1 of the License Agreement, CHOP—and Davidson as an employee of CHOP—were obligated to keep Orphion's reports and data confidential.

154. Both the Licensed Patent Rights and Orphion's confidential reports and data were necessary for Orphion's development of its Pediatric Therapeutic and protected from disclosure by the terms of the License Agreement. The Licensed Patent Rights and the Orphion's confidential reports and data were thus trade secrets under New York law.

155. Davidson and Latus convinced CHOP to purportedly terminate the License Agreement in bad faith—in part on the grounds that Orphion would not be able to meet its milestones without the cGMP Vector Materials that CHOP had refused to provide Orphion in breach of the Purchase Agreement.

156. Davidson and Latus have since used the Licensed Patent Rights in developing their own CLN2 treatment. Indeed, Davidson founded Latus with the purpose of using the Licensed Patent Rights that she knew were held by Orphion under the License Agreement.

157. Because CHOP's termination of the License Agreement was in bad faith and invalid—as Davidson and Latus knew having procured the termination—Davidson and Latus' use of the Licensed Patent Rights was in breach of the License Agreement.

158. Davidson and Latus have also used Orphion's confidential reports and data in developing their CLN2 treatment—including to measure and improve the effectiveness of their own CLN2 treatment.

159. Davidson came to possess the Orphion's confidential reports and data in her capacity as the Chief Scientific and Strategy Officer of CHOP's Clinical Vector Core. Davidson was thus obligated to keep Orphion's confidential reports and data confidential under the License Agreement. Instead, she used them for Latus' business in breach of License Agreement and the confidence in which she received them.

160. As a result of Davidson of Latus misappropriation of Orphion's trade secrets, Orphion lost profits in an amount to be determined at trial, but not less than $100 million from the earning of a PRV and profits on expected revenue of over $500 million in just the first five years of sales.

EIGHTH CAUSE OF ACTION
(Unfair Competition – Against Davidson and Latus)

161. Orphion incorporates by reference the allegations in the above paragraphs.

162. Pursuant to the License Agreement, Orphion acquired the exclusive Licensed Patent Rights from CHOP.

163. These exclusive Licensed Patent Rights included patents and patent applications for "Methods and Vectors for Treating CNS Disorders" and "Methods and Uses for Treating Neurodegenerative Diseases." (Ex. 1 § 2.22, Appendices A & E.)

164. Additionally, the License Agreement also gave Orphion "an exclusive option … to negotiate (a) an exclusive, worldwide, transferable, sublicensable license to any and all Future CHOP IP." (*Id.*, § 3.3.) Future CHOP IP is defined as "all discoveries and inventions that

constitute patentable advancements, developments, or improvements" to CHOP's patents and applications related to the treatment of CLN2. (*Id.*, § 2.8.)

165. Also pursuant to the License Agreement, Orphion provided CHOP and Davidson with confidential reports and data on work that Orphion did in connection with the development of its Pediatric Therapeutic, including regular meetings or teleconferences regarding preclinical work and clinical development plans, audits and ancillary work on the quality and usability of the cGMP Vector Materials, and decks with the results of studies conducted by Orphion.

166. Under Sections 9.9 and 14.1 of the License Agreement, CHOP—and Davidson as an employee of CHOP—were obligated to keep Orphion's reports and data confidential.

167. In 2020 Orphion and CHOP entered into the Purchase Agreement in which Orphion purchased, among other items, 416 vials of cGMP Vector Materials. Under the Purchase Agreement, CHOP agreed to store the cGMP Vector Materials until Orphion requested delivery.

168. The cGMP Vector Materials, the Licensed Patent Rights, and Orphion's confidential reports and data were necessary for Orphion's development of its Pediatric Therapeutic.

169. Davidson, in her work at CHOP, has also made improvements to some of the patents for methods of CLN2 treatment which Orphion, including the development of the AAV-Ep+ vector in her work in CHOP's Clinical Vector Core program. Under the License Agreement, Orphion was entitled to an exclusive opportunity to license this improvement to the Licensed Patent Rights. Instead, Davidson and CHOP have provided the AAV-Ep+ vector technology to Latus for use in its planned CLN2 treatment.

170. Davidson, as the Chief Scientific and Strategy Officer of CHOP's Clinical Vector Core and founder of Latus, knew that Orphion had purchased the cGMP Vector Materials and the

Licensed Patent Rights and that Orphion had shared confidential reports and data with CHOP under the protection of the License Agreement.

171. Nevertheless, in deliberate bad faith, Latus and Davidson converted the cGMP Vector Materials and misappropriated the Licensed Patent Rights and Orphion's confidential reports and data and used them all to develop Latus' own CLN2 treatment.

172. Moreover, by converting and misappropriating Orphion's cGMP Vector Materials and Licensed Patent Rights, Latus caused Orphion's business to collapse and thereby prevented Orphion from creating its own CLN2 treatments—clearing the market for Latus.

173. As a result of Davidson and Latus' unfair competition, Orphion's had to cease operations and was damaged in the amount of its full value, at least $27.2 million as of 2019. And Orphion lost expected profits in an amount to be determined at trial but not less than $100 million from the earning of a PRV and profits on expected revenue of over $500 million in just the first five years of sales.

PRAYER FOR RELIEF

WHEREFORE, Orphion respectfully requests that the Court enter Judgment in favor of Orphion and against Defendants, jointly and severally, for the following relief:

1. Damages of at least $27.2 million for the loss of value of Orphion's business as a result of Defendants' breaches and tortious conduct;

2. Consequential damages of at least $100 million for the loss of the PRV, and losses on profits on expected revenue of over $500 million had Defendants not prevented Orphion from developing its treatment for CLN2 blindness;

3. Punitive damages in an amount to be determined at trial;

4. Prejudgment interest at the New York statutory rate;

5. Reasonable attorneys' fees, costs, and expenses in an amount to be determined at the conclusion of this lawsuit; and

6. Such other relief as the Court may deem just and proper.

Dated: New York, NY
October 2, 2024

SADIS & GOLDBERG LLP

/s/ Ben Hutman

By: Ben Hutman
Kathleen Reilly
551 Fifth Avenue, 21st Floor
New York, New York 10176
Telephone: (212) 573-6675
Email: bhutman@sadis.com

Attorneys for Plaintiff Orphion Therapeutics

EXHIBIT 1

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THE CHILDREN'S HOSPITAL OF PHILADELPHIA PATENT LICENSE AGREEMENT-EXCLUSIVE

This License Agreement (the "**Agreement**") is entered into this 28th day of October, 2019 (the "**Effective Date**"), by and between Orphion Therapeutics having a principal place of business at 57 Meadow Woods Road, Great Neck, NY 11020_("**Orphion**"), and The Children's Hospital of Philadelphia, a non-profit entity organized and existing under the laws of Pennsylvania and having a principal place of business at 3401 Civic Center Boulevard, Philadelphia, PA 19104. Orphion and its Affiliates are together referred to herein as "**Licensee.**" The Children's Hospital of Philadelphia and its Affiliates are together referred to herein as "**CHOP.**" **CHOP** and **Licensee** may be referred to herein collectively as the "**Parties**" or individually as "**Party**."

CHOP and **Licensee** agree as follows:

1. BACKGROUND

1.1. In the course of conducting biomedical and behavioral research, **CHOP** investigators made inventions that may have commercial applicability (defined herein as the "**Technology**").

1.2. By assignment of rights from **CHOP** employees and other inventors, **CHOP** owns any and all intellectual property rights claimed in any United States and foreign patent applications or patents corresponding to the assigned inventions that are listed in **Appendix A** and co-owns the **CHOP Co-Owned IP** (as defined herein). **CHOP** also owns any and all tangible embodiments of these inventions actually reduced to practice by **CHOP** investigators.

1.3. **CHOP** desires to transfer these inventions to the private sector through commercialization licenses to facilitate the commercial development of products and processes for public use and benefit.

1.4. **Licensee** desires to acquire commercialization rights to certain of these inventions and the corresponding intellectual property rights in order to develop processes, methods, or marketable products and such activities are expected to provide for public use and benefit of these inventions.

1.5. **Licensee** and **CHOP** will enter a sponsored research agreement in parallel with this **Agreement** to engage in further research related to the **Technology**

2. DEFINITIONS AND INTERPRETATION

2.1. **"Affiliates"** shall mean, with respect to any person or entity, any other person or entity, which controls, is controlled by or is under common control with such person or entity. A person or entity shall be regarded as in control of another entity if it owns or controls at least fifty percent (50%) of the equity securities of the subject entity entitled to vote in the election of directors (or, in the case of an entity that is not a corporation, for the election of the corresponding managing authority), provided, however, that the term "Affiliate" shall not include subsidiaries or other

entities in which a Party or its Affiliates owns a majority of the ordinary voting power necessary to elect a majority of the board of directors or other governing board, but is restricted from electing such majority by contract or otherwise, until such time as such restrictions are no longer in effect.

2.2. "**CHOP Know-How**" means any non-public information, data, results, protocols, techniques, methods, processes, chemical and biological materials, formulations, information, documents, studies, regulatory approvals,databases; ideas; discoveries; practices; methods; tests; techniques; processes; formulations; formulae; knowledge; skill; research tools; software programs; algorithms; studies; drawings; plans; designs; diagrams; sketches; technology; documentation; specifications; sourcing information; assays; procedures including quality control and testing procedures;specifications; or descriptions of any type whatsoever, in any tangible or intangible form whatsoever, whether or not patentable (a) directly related to development, manufacture, or use of the **Licensed Patent Rights**, (b) discovered, conceived, created, or invented as a result of, or arose out of, the research conducted at **CHOP** by Dr. Beverly Davidson or those under her direct supervision, direction, or control,owned or controlled by **CHOP**, free from any exclusive obligations to any **Third Parties** other than the United States **Government** or to any individual under the Bayh-Dole Act as of the **Effective Date** or at any time thereafter during the **Term** of the **Agreement** that is reasonably necessary or useful for the development, manufacture, commercialization or use of the **Licensed Processes** or **Licensed Products**, provided that **CHOP Know How** does not include **Licensed Patent Rights**.

2.3. **"CHOP Co-owned IP"** shall mean the patent applications, listed in **Appendix E,** co-owned by **CHOP** and Spark Therapeutics titled, *Methods and Vectors for Treating CNS Disorders,* all provisional applications, substitute applications, divisions, continuations, continuations-in-part, inventor's certificates, patents of addition of any of the foregoing; any registrations, term restorations, renewals, supplemental protection certificates, reissues, reexaminations, and extensions of all such patents; and all priority applications of any of the foregoing; all counterpart foreign applications; all applications claiming priority from or the benefit of any of the foregoing; and all patents issuing from any of the foregoing.
"CHOP Co-owned IP" shall include all applications claiming priority from or the benefit of any of the foregoing including continuation-in-part applications; and all patents issuing from any of the foregoing; provided, however, that continuation-in-part applications are included only to the extent of claims therein that do not rely on the priority and disclosure of new matter that is not the subject matter disclosed in the aforementioned patent application.

2.4. **"Commercial Development Plan"** means the written commercialization plan attached as **Appendix D**.

2.5. "**Confidential Information**" means any proprietary or confidential information, technical data, **Know-How**, research, product plans, developments, inventions, processes, protocols, formulas, marketing plans, strategies, customer lists, and other information or material that are disclosed or provided by a **Party** to the other **Party**, in writing, orally, electronically, or graphically or inspection of documents or other

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tangible property in connection with this **Agreement** regardless of whether any of the foregoing are marked "confidential" or "proprietary" or communicated to the other by the disclosing Party in oral, written, graphic, or electronic form. The recipient of **Confidential Information** shall be under no obligation with respect to any information which: (a) at the time of disclosure is available to the public; or (b) after disclosure becomes available to the public through no fault of the recipient, provided that the obligation of the recipient shall cease only after the date on which such information has become available to the public; or (c) the recipient can demonstrate through tangible evidence was in its possession before receipt from the disclosing party; or (d) is disclosed to the recipient without restriction on disclosure by a **Third Party** who has the lawful right to disclose such information.

2.6. "**First Commercial Sale**" means the initial transfer by or on behalf of **Licensee** or its sublicensees of **Licensed Products** or the initial rendering of services under a **Licensed Process** by or on behalf of **Licensee** or its sublicensees in exchange for cash or some equivalent to which value can be assigned for the purpose of determining **Net Sales**.

2.7. "**Future CHOP Know How**" means any **Know-How** generated following the **Effective Date** during the **Term** of the **Agreement** in each case that satisfy the following: (a) directly necessary or useful to practice the **Licensed Patent Rights** in the **Licensed Field of Use**, (b) is controlled by **CHOP** following the **Effective Date**, free from any exclusive obligations to any **Third Parties** (other than the United States government, provided that any rights granted to **Future CHOP Know-How** hereunder will be subject to the rights of the United States **Government** or to any individual under the Bayh-Dole Act) and (c) is discovered, conceived, created, or invented as a result of, or arising out of, the research conducted at **CHOP** by Dr. Beverly Davidson or those under her direct supervision, direction, or control. For the avoidance of doubt, **Future CHOP Know-How** does not include **Future CHOP IP** and does not include **Know-How** generated by the CHOP Center for Cellular and Molecular Therapeutics Research Vector Core that is directed to platform or vector technology that is not used in the manufacturing of **Licensed Products** or components.

2.8. "**Future CHOP IP**" means all discoveries and inventions that constitute patentable advancements, developments or improvements to the **Technology** that are directly necessary or useful to practice the **Licensed Patent Rights** in the **Licensed Field of Use**, in each case that satisfy all of the following: (a) are controlled by **CHOP** following the **Effective Date**, free from any exclusive obligations to any **Third Parties** (other than the United States government, provided that any rights granted to **Future CHOP IP** hereunder will be subject to the rights of the United States **Government** or to any individual under the Bayh-Dole Act) and (b) are invented as a result of, or arising out of, the research conducted in whole at **CHOP** by Dr. Beverly Davidson or those under her direct supervision, direction, or control.

2.9. "**Government**" means the Government of the United States of America and its respected agencies such as the Department of Health and Human Services.

2.10. "**Know-How**" means any non-public information, data, results, protocols, techniques, methods, processes, chemical and biological materials, formulations, information,

documents, studies, regulatory approvals, databases; ideas; discoveries; practices; methods; tests; techniques; processes; formulations; formulae; knowledge; skill; research tools; software programs; algorithms; studies; drawings; plans; designs; diagrams; sketches; technology; documentation; specifications; sourcing information; assays; procedures including quality control and testing procedures; specifications; or descriptions of any type whatsoever, in any tangible or intangible form whatsoever, whether or not patentable.

2.11. "**Licensed Fields of Use**" means all therapeutic, prophylactic, and diagnostic applications for any indication.

2.11 "**Licensed Patent Rights**" shall mean U.S. patent application and patents listed in **Appendix A**, all provisional applications, substitute applications, divisions, continuations, continuations-in-part, inventor's certificates, patents of addition of any of the foregoing; any registrations, term restorations, renewals, supplemental protection certificates, reissues, reexaminations, and extensions of all such patents; and all priority applications of any of the foregoing; all counterpart foreign applications; all applications claiming priority from or the benefit of any of the foregoing; and all patents issuing from any of the foregoing.
Licensed Patent Rights shall include all applications claiming priority from or the benefit of any of the foregoing including continuation-in-part applications; and all patents issuing from any of the foregoing; *provided, however*, that continuation-in-part applications are included only to the extent of claims therein that do not rely on the disclosure of new matter that is not the subject matter disclosed in patents listed in Appendix A above.

2.12 "**Licensed Process(es)**" shall mean processes which, in the course of being made, used, offered for sale, sold, or imported would, in the absence of this **Agreement**, infringe one or more claims of the **Licensed Patent Rights** or **CHOP Co-Owned IP** that have not been held invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction; *provided, however*, that for the purposes of any payments or **First Commercial Sale** under this **Agreement**, **Licensed Processes** shall not include methods of manufacturing, preparing, formulating, packaging, or synthesizing **Licensed Products** or any components thereof.

2.13 "**Licensed Product(s)**" means products which, if manufactured, used, offered for sale, sold, or imported would, in the absence of this **Agreement**, infringe one or more claims of the **Licensed Patent Rights** or **CHOP Co-Owned IP** that have not been held invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.

2.14 "**Licensed Territory**" means worldwide.

2.15 **"Milestones"** mean the performance milestones that are set forth in **Appendix C**

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2.16 "**Net Sales**" means, with respect to any **Licensed Product or Licensed Processes**, the gross amounts received on arm's length sales of such **Licensed Product** by **Licensee** or its sublicensees to a **Third Party** or of services rendered by **Licensee** or its sublicensees to a **Third Party** under such **Licensed Processes**, each less the following customary deductions to the extent specifically and solely allocated to the sale of such **Licensed Product or** services under such **Licensed Processes** and actually taken, paid, accrued, allowed, or included in the gross sales prices with respect to such sales:

(a) discounts (including trade, cash, quantity, prime vendor, and patient program discounts), retroactive price reductions, charge-back payments and rebates granted to managed health care organizations or to federal, state and local governments, their agencies, buying groups, pharmacy benefit management companies, health care insurance carriers, institutions, and purchasers and reimbursers or to trade customers;

(b) adjustments, credits, or allowances actually granted upon claims, damaged goods, rejections or returns of such **Licensed Product or** services under such **Licensed Processes**, billing adjustments, billing errors, and government requirements including such **Licensed Product** or services under such **Licensed Processes** returned in connection with recalls or withdrawals;

(c) warehousing costs and expenses and freight out, postage, shipping and insurance charges for delivery of such **Licensed Product** or services under such **Licensed Processes**;

(d) taxes or duties (excluding income taxes) levied on, absorbed or otherwise imposed on the sale of such **Licensed Product** or services under such **Licensed Processes**, including user fees, value-added taxes, excise taxes, customs and other duties, or other governmental charges otherwise imposed upon the billed amount including transportation, as adjusted for rebates and refunds, to the extent not paid by the **Third Party**;

(e) **Third Party** distributor fees;

(f) **Uncollectable Amounts** receivable; and

Sales and other transfers of **Licensed Product** between, and any services under **Licenced Processes** rendered to, any of **Orphion**, its **Affiliates** and sublicensees will not give rise to **Net Sales**, but rather the subsequent sale of **Licensed Product** or rendering of services under **Licensed Processes** to **Third Parties** shall. **Net Sales** for any combination product or service will be calculated on a country-by-country basis by multiplying actual **Net Sales** of such combination product by the fraction A/B, where A is the weighted average price paid for the **Licensed Product** or service under **Licensed Processes** contained in such combination product or service if such **License Product** or service under such **Licensed Processes** were sold separately in finished form in such country, and B is the weighted average invoice price paid for such combination product or service in such country. If such **Licensed Product** or service under such **Licenced Processes** is not sold separately in finished form in

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such country, the **Parties** will determine **Net Sales** for such **Licensed Product** or service under such **Licensed Processes** by mutual agreement based on the relative contribution of such **Licensed Product** or or service under such **Licensed Processes** and each such other active ingredients in such combination product or such other services in such combination service in accordance with the above formula, and will take into account in good faith any applicable allocations and calculations that may have been made for the same period in other countries.

For the avoidance of doubt, sales for clinical studies purposes, test marketing, or named patient, compassionate, or similar use will not be considered to constitute **Net Sales**.

2.17 "**Person**" means any natural or non-natural person.

2.18 "**Practical Application**" means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case or a machine or system; and in each case, under such conditions as to establish that the invention is utilized and that its benefits are to the extent permitted by law or government regulations available to the public on reasonable terms.

2.19 "**Research License**" means a nontransferable, nonexclusive license to make and to use the **Licensed Products** or **Licensed Processes** as defined by the **Licensed Patent Rights** or **CHOP Co-Owned IP** for purposes of research and not for purposes of commercial manufacture or distribution or in lieu of purchase.

2.20 "**Royalty Term**" means, with respect to each **Licensed Product(s)** or services under **Licensed Process(es)** and each country or other jurisdiction in the **Licensed Territory**, the period beginning on the **Effective Date** and ending on the later to occur of (a) the expiration, invalidation or abandonment of the last **Licensed Patent Rights** or **CHOP Co-Owned IP** or (b) ten (10) years from the **First Commercial Sale**.

2.21 "**Sublicense Income**" means monetary or equity income received by **Licensee** or its **Affiliates** in consideration for a **Sublicense** or other agreement providing the right to negotiate or obtain a **Sublicense**. **Sublicense Income** includes income received from a **Sublicensee** in the form of license issue fees, milestone payments and the like but specifically excludes (a) amounts received by **Licensee** or any of its **Affiliates** as payment for the cost of manufacture or supply of any **Licensed Product** or the provision or performance of a **Licensed Process** by such **Licensee** or any of its **Affiliates**, (b) royalties on the sale or distribution of **Licensed Product** or provision or performance of a **Licensed Process**, including royalties paid as a percentage of **Net Sales**, (c) amounts received by **Licensee** or any of its **Affiliates** in connection with achievement of a **Milestone**, up to the amount of any milestone payment made to **CHOP** under Paragraph 6.4 that is triggered by the achievement of the same **Milestone** (so that amounts received by Licensee or any of its Affiliates that exceed the amount of the milestone payment under

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Paragraph 6.4 shall be included in "**Sublicense Income**"), (d) payments received for funding research and development services pursuant to a written research and development agreement between **Licensee** (or one of its **Affiliates**) and **Sublicensee** up to the fair market value of such services, (e) reimbursements of documented out-of-pocket patent expenses incurred by **Licensee** or any of its **Affiliates** on a passthrough basis for reimbursement of patent prosecution or patent maintenance expenses, and (f) any income that is not monetary or equity income.

2.22 "**Technology**" means certain innovative technologies entitled, *Method of treatment of a lysosomal storage disease (CLN2) with AAV2-TPP1 via subretinal administration, Gene Transfer Compositions, Methods and Uses for Treating Neurodegenerative Diseases*, and *Overcoming Limitations Inherent in Sulfamidase to Improve MPS IIIA Gene Therapy* as disclosed under **CHOP** ID:1136-19, 0933-17, and 0904-17 respectively and each of which were created in the course of research at **CHOP** by Beverly Davidson, Yonghong Chen, and Luis Tecedor (hereinafter the "**Inventors**") and as further described in the patent applications listed in **Appendix A. Technology** also means *Methods and Vectors for Treating CNS Disorders* as disclosed under CHOP ID: 0932-17 which was created by Beverly Davidson and Katherine High, as further described in the patent applications in **Appendix E.**

2.23 "**Third Party**" means any **Person** other than **CHOP** or **Licensee.**

2.24 "**Valid Claim**" means (a) a claim of an issued **Licensed Patent Right** or **CHOP Co-Owned IP** that has not (i) expired or been canceled, (ii) been declared invalid or unenforceable by a decision of a court or other appropriate body of competent jurisdiction, from which no appeal is or can be taken, (iii) been admitted to be invalid or unenforceable through reissue, disclaimer, or otherwise, or (iv) been abandoned, disclaimed, or dedicated to the public; and (b) a claim included in a pending patent application that is being actively prosecuted and that has not been (i) canceled, (ii) withdrawn from consideration, (iii) finally determined to be unallowable by the applicable governmental authority from which no appeal is or can be taken, or (iv) abandoned or disclaimed.

Notwithstanding the foregoing clause (b), in the event that a pending claim in a pending patent application is rejected and does not issue in an issued **Licensed Patent Right** or **CHOP Co-Owned IP** within five (5) years after the first substantive office action, such a pending claim will not be a **Valid Claim**, unless and until such pending claim subsequently issues in an issued **Licensed Patent Right** or **CHOP Co-Owned IP**, at which time such claim may again be a **Valid Claim** as of the date of issuance of such **Licensed Patent Right** or **CHOP Co-Owned IP** if such claim also meets the requirements of this Article.

2.25 "Herein", "hereof", and "hereunder" and words of like import refer to this Agreement as a whole and not to any particular provision of this Agreement.

2.26 "Include", "includes", or "including" shall be deemed to be followed by the words "without limitation", whether or not they are in fact followed by those words or words of like import.

2.27 "Writing", "written", and comparable terms refer to printing, typing and other means of reproducing words (including electronic media) in a visible or readable (electronically or otherwise) form.

2.28 Agreement References. References to any agreement or contract are to that agreement or contract as amended, modified or supplemented in writing from time to time in accordance with the terms hereof and thereof.

2.29 Ambiguities. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision.

2.30 Capitalization. Any capitalized terms used in any Schedule or Exhibit but not otherwise defined therein shall have the meaning as defined in this Agreement.

2.31 Date References. References from or through any date mean, unless otherwise specified, from and including or through and including, respectively.

2.32 Gender. Unless the context of this Agreement otherwise requires, words of one gender include the other gender.

2.33 Headings. Headings and captions of the Articles and Paragraphs hereof are for convenience only and are not to be used in the interpretation of this Agreement.

2.34 Joint and Several Obligations. Unless specified otherwise in this Agreement, the obligations of any Party consisting of more than one person are joint and several.

2.35 No Strict Construction. This Agreement has been prepared jointly and shall not be strictly construed against either Party.

2.36 Number of Days. Whenever this Agreement refers to a number of days, unless otherwise specified, such number shall refer to calendar days.

2.37 Person References. References to any Person include the successors and permitted assigns of that Person.

2.38 References to Parts of this Agreement. References to Articles and Paragraphs are to Articles and Paragraphs of this Agreement unless otherwise specified.

2.39 Schedules, Exhibits, and Appendices. All Schedules, Exhibits, and Appendices annexed hereto or referred to herein are hereby incorporated in and made a part of this Agreement as if set forth in full herein.

2.40 Singular/Plural. Any singular term in this Agreement shall be deemed to include the plural, and any plural term the singular.

2.41 United States Dollars. References in this Agreement to "Dollars" or "$" shall mean the legal tender of the United States of America.

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2.42 "**Uncollectible Amounts**" means amounts owed and unpaid to Licensee, its Affiliates or its Sublicensees, as applicable, for previously sold Licensed Products or Licensed Processes, which unpaid amounts Licensee, its Affiliates or its Sublicensees, as applicable, have attempted to collect using efforts at least as diligent as those efforts that Licensee, its Affiliates or its Sublicensees, as applicable, use in attempting to collect other overdue debts; *provided that* (i) such amounts have been formally designated in accordance with US GAAP calculation as "uncollectible" or "overdue" in accordance with Licensee's, its Affiliates' or its Sublicensees' internal accounting procedures, and (ii) that such allowance shall not be applicable in the event and to the extent any such designated amounts are ultimately collected.

3. GRANT OF RIGHTS

3.1. **CHOP** hereby grants and **Licensee** accepts, subject to the terms and conditions of this **Agreement**, an exclusive (even as to **CHOP**), transferable , sublicenseable license under the **Licensed Patent Rights** and **CHOP's** rights in the **CHOP Co-owned IP** in the **Licensed Territory** to make and have made, to use and have used, to offer for sale and have offered for sale, to sell and have sold, and to import and have imported any **Licensed Products** in the **Licensed Fields of Use** and to make and have made, to use and have used, to offer for sale and have offered for sale, to sell and have sold, and to import and have imported services under any **Licensed Processes** in the **Licensed Fields of Use**.

3.2. **CHOP** hereby grants and **Licensee** accepts, subject to the terms and conditions of this **Agreement**, a non-exclusive, transferable (pursuant to Paragraph 15.7) license under the **CHOP Know-How** in the **Licensed Territory** to make and have made, to use and have used, to offer to sell and have offered to sell, to sell and have sold, and to import and have imported any **Licensed Products** in the **Licensed Fields of Use** and to make and have made, to use and have used, to offer for sale and have offered for sale, to sell and have sold, and to import and have imported any **Licensed Processes** in the **Licensed Fields of Use** and to use and have used, to offer to sell and have offered to sell, to sell and have sold, and to import and have imported any materials transferred by or on behalf of **CHOP** to **Licensee** to research, develop, use and have used, to offer to sell and have offered to sell, to sell and have sold, and to import and have imported any **Licensed Products** in the **Licensed Fields of Use** and to make and have made, to use and have used, to offer for sale and have offered for sale, to sell and have sold, and to import and have imported any **Licensed Processes** in the **Licensed Fields of Use**.

3.3. **Future CHOP IP and Future CHOP Know-How.** Subject to the terms and conditions of this **Agreement**, **CHOP** hereby grants to **Licensee** an exclusive option during the **Term** to negotiate (a) an exclusive, worldwide, transferable, sublicenseable license to any and all **Future CHOP IP** and (b) a non-exclusive, worldwide license to **Future CHOP Know-How** (the "**Option**"). **Licensee** may elect to exercise the **Option** for a particular **Future CHOP IP** or **Future CHOP Know-How** by giving written notice to **CHOP** no later than sixty (60) days after **CHOP**'s Office of Technology Transfer provides a copy of the a written disclosure in sufficient detail to enable Licensee to understand and make an informed decision on the exercise of the Option for such **Future CHOP IP** or **Future CHOP Know-How**

to **Licensee**. **CHOP** shall inform **Licensee** of any **Future CHOP IP** or **Future CHOP Know-How**. Upon exercise of the **Option** by **Licensee** with respect to a particular **Future CHOP IP** or **Future CHOP Know-How**, the **Parties** shall negotiate in good faith a license agreement for such **Future CHOP IP** or **Future CHOP Know-How** on terms comparable to the terms of this **Agreement** (with adjustments for any differences in value between such **Future CHOP IP** or **Future CHOP Know-How** and the intellectual property licensed hereunder) for a period of (a) three (3) months after the date that the **Licensee** exercises its **Option** over such **Future CHOP IP** or **Future CHOP Know-How.** The license agreement negotiation period may be extended for an additional three (3) months upon mutual written agreement of the **Parties**, after which and assuming the **Parties** do not enter into license or other agreement, all rights of **Licensee** relating to such particular **Future CHOP IP** or **Future CHOP Know-How** under this **Agreement** shall terminate.

3.4. This **Agreement** confers no license or rights by implication, estoppel, or otherwise under any patent applications or patents of **CHOP** other than **Licensed Patent Rights** regardless of whether such patents are dominant or subordinate to **Licensed Patent Rights**.

4. SUBLICENSING

4.1. Upon written approval by **CHOP**, which approval will not be unreasonably withheld, conditioned, or delayed, **Licensee** may enter into sublicensing agreements under the **Licensed Patent Rights** or **CHOP's** rights in **the CHOP Co-Owned IP**.

4.2. **Licensee** agrees that any sublicenses granted by it shall provide that the obligations to **CHOP** of Article 2 and Paragarphs 5.1-5.3, 8.1, 10.1, 10.2, 12.5, 13.7-13.9, and Article 14 of this **Agreement** shall be binding upon the sublicensee as if it were a **Party** to this **Agreement**. **Licensee** further agrees to attach copies of these Articles to all sublicense agreements.

4.3. Any sublicenses granted by **Licensee** shall provide for the termination of the sublicense, or the conversion of the sublicense to a license directly between such sublicensees and **CHOP**, at the option of the sublicensee upon termination of this **Agreement** under Article 13. Such conversion is subject to **CHOP** approval and is contingent upon acceptance by the sublicensee of the remaining provisions of this **Agreement**; provided, however, that **CHOP** shall not add any further provisions to the Agreement as a condition to such conversion.

4.4. **Licensee** agrees to forward to **CHOP** a copy of each fully executed sublicense agreement postmarked within thirty (30) days of the execution of such agreement, subject to any confidentiality obligations of Licensee to any sublicensee. To the extent permitted by law, **CHOP** agrees to maintain each such sublicense agreement in confidence.

5. CHOP REQUIREMENTS AND RESERVED GOVERNMENT RIGHTS

5.1. **CHOP** reserves an irrevocable, nonexclusive, nontransferable, royalty-free **Research License** for the practice of all inventions licensed under the **Licensed Patent Rights**

and **CHOP Co-Owned IP** throughout the world for **CHOP**'s non-commercial educational, research, and clinical activities. Prior to the **First Commercial Sale**, **Licensee** agrees to provide **CHOP** reasonable quantities of **Licensed Products** or materials made through the **Licensed Processes** for **CHOP** research use, provided that there is a sufficient amount of **Licensed Product** to meet **Orphion's** development and commercialization plans.

5.2. **Licensee** agrees that Licensed Products used or sold in the United States and products produced through use of **Licensed Processes** shall be manufactured substantially in the United States, unless a written waiver is obtained in advance from the appropriate **Government** agency if **Licensed Patent Rights** or **CHOP Co-Owned IP** were supported by said **Government** agency.

5.3. In addition to the reserved license of Paragraph 5.1 above, **CHOP** reserves the right to grant such non-exclusive, non-transferable **Research Licenses** to non-commercial **Third Parties** directly on reasonable terms.

6. CONSIDERATION

6.1. During the **Royalty Term**, **Licensee** agrees to pay to **CHOP** a noncreditable, nonrefundable license issue fee as set forth in **Appendix B** on the earlier of thirty (30) days post **Financing** or on June 30th 2020. For clarification, "**Financing**" means investment of at least $1,000,000.

6.2. During the **Royalty Term**, **Licensee** agrees to pay to **CHOP** a nonrefundable minimum annual royalty for the entire Territory as set forth in **Appendix B**. The minimum annual royalty is due and payable on January 1 of each calendar year and may be credited against any earned royalties due for sales made in that year. The first minimum annual royalty payment due may be prorated according to the fraction of the calendar year remaining between the date of **First Commercial Sale** and the next subsequent January 1. The first minimum annual royalty payment commences on the **First Commercial Sale** in the **Territory** of the first **Licensed Product** or rendering of services under a **Licensed Process** and is due and payable within thirty (30) days of the date of such **First Commercial Sale**.

6.3. During the **Royalty Term**, **Licensee** agrees to pay **CHOP** earned royalties as set forth in **Appendix B**.

6.4. During the **Royalty Term**, **Licensee** agrees to pay **CHOP** milestone payments as set forth in **Appendix B**.

6.5. During the **Royalty Term**, **Licensee** agrees to pay **CHOP** sublicensing royalties as set forth in **Appendix B**.

6.6. No multiple royalties shall be payable because any **Licensed Products** or **Licensed Processes** are covered by more than one of the **Licensed Patent Rights** or **CHOP Co-Owned IP**, and no multiple royalties shall be payable because any given unit of a **Licensed Product** is sold more than once.

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6.7. Other than under any agreements, contracts, or licenses with Spark Therapeutics, in the event that **Licensee** requires an additional license from a **Third Party** or other payments are made to a **Third Party** for the right to research, develop, use, make, have made, sell, offer for sale, import, or commercialize and have commercialized the **Licensed Products or** to render services under **Licensed Processes**, (a) the earned royalty payment due pursuant to Paragraph 6.3 shall be reduced by the lesser of (i) the earned royalties paid to such **Third Party** or (ii) 50% of the earned royalties paid to **CHOP**, (b) the milestone payment due pursuant to Paragraph 6.4 shall be reduced by the lesser of (i) any milestone payments paid to such **Third Party** or (ii) 50% of the milestone payments paid to **CHOP**, and (c) the sublicensing royalties pursuant to Paragraph 6.5 shall be reduced by the lesser of (i) the sublicensing royalties paid to such **Third Party** or (ii) 50% of the sublicensing royalties paid to **CHOP**.

6.8. If earned royalties are payable under this Article 6 on **Net Sales** of a particular **Licensed Product** after the expiration of all **Licensed Patent Rights** or **CHOP Co-owned IP** (including any applicable patent term extension) having at least one **Valid Claim** covering the manufacture, use, sale, offer for sale, or importation of such **Licensed** Product or the rendering of services under the **Licensed Processes**, then the earned royalties payable on **Net Sales** of such **Licensed Product** or **Licensed Processes** will be reduced, on a country-by-country basis, by fifty percent (50%) after the date of expiration of all such **Licensed Patent Rights** or **CHOP Co-owned IP**. However, in no event shall the royalty adjustments under this Paragraph 6.9 be applied to reduce the amount payable to **CHOP** with respect to the **Licensed Product** or **Licensed Processes** to less than the minimum annual royalty of twenty-five thousand dollars ($25,000 USD) as pursuant to Paragraph 6.2.

7. PATENT FILING, PROSECUTION, AND MAINTENANCE

7.1. **CHOP** agrees to take responsibility for, but to consult with, the **Licensee** in the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights**, and to furnish copies of relevant patent-related documents to **Licensee**.

7.2. Each **Party** shall promptly inform the other as to all matters that come to its attention that may affect the preparation, filing, prosecution, or maintenance of the **Licensed Patent Rights** and permit each other to provide comments and suggestions with respect to the preparation, filing, prosecution, and maintenance of **Licensed Patent Rights**, which comments and suggestions shall be considered by the other **Party**.

7.3. **CHOP** will keep **Licensee** reasonably informed in the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in **CHOP Co-Owned IP** and will furnish copies of relevant patent-related documents to **Licensee**.

7.4. With regard to expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the **Licensed Patent Rights** incurred by **CHOP** prior to the **Effective Date** of this **Agreement**,

Licensee shall pay to **CHOP** an amount equivalent to such patent expenses previously incurred by **CHOP** according to the following schedule: **Licensee** shall pay to **CHOP** $52,000 within thirty (30) days of the **Effective Date** and **Licensee** shall pay to **CHOP** $65,409.11 on the earlier of thirty (30) days post **Financing** or on June 30th 2020. For clarification, "**Financing**" means investment of at least $1,000,000.

7.5. With regard to expenses associated with the preparation, filing, prosecution, and maintenance of **CHOP Co-Owned IP**, both previously incurred and ongoing costs that are incurred by **CHOP**, **Licensee** shall pay to **CHOP**, on the earlier of thirty (30) days post **Financing** or on June 30th 2020, an amount equivalent to such previously incurred by **CHOP** and ongoing patent expenses incurred by **CHOP**. For clarification, "**Financing**" means investment of at least $1,000,000.

7.6. With regard to expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the **Licensed Patent Rights** incurred by **CHOP** on or after the **Effective Date** of the **Agreement**, **Licensee** will pay **CHOP**, on the earlier of thirty (30) days post **Financing** or on June 30th 2020, an amount equivalent to all such patent expenses incurred by **CHOP**. For clarification, "**Financing**" means investment of at least $1,000,000.

7.7. **Licensee** may elect to surrender its rights in any country of the **Licensed Territory** under any **Licensed Patent Rights** or **CHOP Co-Owned IP** upon sixty (60) days written notice to **CHOP ("Effective Date of Termination")** and owe no payment obligation under Paragraphs 7.4-7.6 for patent-related expenses incurred in that country after the **Effective Date of Termination** of such written notice.

8. RECORD KEEPING

8.1. **Licensee** agrees to keep accurate and correct records of **Licensed Products** and made, used, or sold and **Licensed Processes** practiced under this **Agreement** appropriate to determine the amount of royalties due **CHOP**. Such records shall be retained for at least three (3) years following a given reporting period. They shall be available during normal business hours for inspection at the expense of **CHOP** by an accountant or other designated auditor selected by **CHOP** and approved by **Licensee** for the sole purpose of verifying reports and payments hereunder. The accountant or auditor shall only disclose to **CHOP** information relating to the accuracy of reports and payments made under this **Agreement**. If an inspection shows an underreporting or underpayment in excess of ten percent (10%) for any twelve (12) month period and Licensee does not dispute such underreporting or underpayment, then **Licensee** shall reimburse **CHOP** for the cost of the inspection at the time **Licensee** pays the unreported royalties, including any late charges as required by Paragraph 9.8 of this **Agreement**. All payments required under this Paragraph shall be due within thirty (30) days of the date **CHOP** provides **Licensee** notice of the payment due. No period may be audited by or on behalf of **CHOP** more then once, and no period more than three (3) years before any request by **CHOP** to audit under this Paragraph 8.1 may be audited under this Paragraph 8.1.

9. REPORTS ON PROGRESS, BENCHMARKS, SALES, AND PAYMENTS

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9.1. Within thirty (30) days of the **Effective Date** of this **Agreement**, **Licensee** will provide to **CHOP** the **Commercial Development Plan** at **Appendix D**, under which **Licensee**, as of the **Effective Date**, intends to bring the subject matter of the **Licensed Patent Rights** and **CHOP Co-Owned IP** to the point of **Practical Application.** This **Commercial Development Plan** is hereby incorporated by reference into this **Agreement**. As per the Paragraph 9.2 of this Agreement, this **Commercial Development Plan** may be amended by **Licensee,** acceptance of which by **CHOP** may not be denied, conditioned, or delayed unreasonably.

9.2. **Licensee** shall provide written annual reports on its product development progress or efforts to commercialize under the then current **Commercial Development Plan** within sixty (60) days after December 31 of each calendar year. These progress reports shall include: progress on research and development, status of applications for regulatory approvals, manufacturing, sublicensing, marketing, and sales during the preceding calendar year, as well as plans for the present calendar year. **CHOP** also encourages these reports to include information on any of **Licensee**'s public service activities that relate to the **Licensed Patent Rights** and **CHOP Co-Owned IP**. If reported progress differs from that projected in the **Commercial Development Plan** and **Milestones**, **Licensee** shall explain the reasons for such differences. **Licensee** agrees to provide any additional information reasonably required by **CHOP** to evaluate **Licensee**'s performance under this **Agreement**. **Licensee** may amend the **Milestones** at any time upon written consent by **CHOP**, such consent not to be unreasonably withheld, conditioned, or delayed. **CHOP** shall not unreasonably withhold, condition, or delay approval of any request of **Licensee** to extend any time periods in a **Commercial Development Plan** if such request is supported by a reasonable showing by **Licensee** of diligence in its performance under the **Commercial Development Plan** and toward bringing a **Licensed Product** or **Licensed Processes** to the point of **Practical Application**.

9.3. **Licensee** shall report to **CHOP** the date of the **First Commercial Sale** of each **Licensed Product** or Licensed Processes in each country in the **Licensed Territory** within thirty (30) days of such occurrence.

9.4. **Licensee** shall submit to **CHOP** within sixty (60) days after each calendar half-year ending June 30 and December 31 a royalty report setting forth for the preceding half-year period the amount of the **Licensed Products** sold or services under **Licensed Processes** practiced by or on behalf of **Licensee** in each country within the **Licensed Territory**, the **Net Sales**, and the amount of royalty accordingly due. With each such royalty report, **Licensee** shall submit payment of the earned royalties due. If no earned royalties are due to **CHOP** for any reporting period, the written report shall so state. The royalty report shall be certified as correct by an authorized officer of **Licensee** and shall include a detailed listing of all deductions made under Paragraph 2.10 to determine **Net Sales** made under Article 6 to determine **Net Sales** made under Article 6 to determine royalties due.

9.5. **Licensee** agrees to forward semi-annually to **CHOP** a copy of such reports received by **Licensee** from its sublicensees during the preceding half-year period as shall be pertinent to a royalty accounting to **CHOP** by **Licensee** for activities under the sublicense.

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9.6. Royalties due under Article 6 shall be paid in U.S. dollars. For conversion of foreign currency to U.S. dollars, the conversion rate shall be the New York foreign exchange rate quoted in The Wall Street Journal on the day that the payment is due. Any loss of exchange, value taxes, or other expenses incurred in the transfer or conversion to U.S. dollars shall be paid entirely by **Licensee**. The royalty report required by Paragraph 9.4 of this **Agreement** shall accompany each such payment and a copy of such report shall also be mailed to **CHOP** at its address for notices indicated on the signature page of this **Agreement**.

9.7. **Licensee** shall be solely responsible for determining if any tax on royalty income is owed by **Licensee** outside the United States and shall pay any such tax and be responsible for all filings with appropriate agencies of foreign **Governments**. **CHOP** will be responsible for any and all income or other similar taxes owed by **CHOP** and required by applicable law to be withheld or deducted from any payments made by or on behalf of **Licensee** to **CHOP** hereunder ("**CHOP Withholding Taxes**"), and **Licensee** may deduct from any amounts that **Licensee** is required to pay hereunder an amount equal to such **CHOP Withholding Taxes,** provided that **Licensee** is required by a governmental authority to pay such amounts on **CHOP's** behalf. **CHOP** will provide **Licensee** with any information available to **CHOP** that is necessary to determine the **CHOP** Withholding Taxes. Such **CHOP Withholding Taxes** will be paid to the proper taxing authority for **CHOP**'s account, and evidence of such payment that is satisfactory to **CHOP** will be sent to **CHOP** within one (1) month of such payment. The **Parties** will cooperate with each other in seeking relief or reduction in the deduction or withholding of any tax under any double taxation or other similar treaty or agreement from time to time in force and in seeking to receive a refund of any withholding tax or to claim a foreign tax credit.

9.8. Late charges will be assessed by **CHOP** as additional royalties on any overdue payments at a rate of one (1) percent per month compounded monthly. The payment of such late charges shall not prevent **CHOP** from exercising any other rights it may have as a consequence of the lateness of any payment.

9.9. All plans and reports required by this Article 9 and marked confidential by **Licensee** shall, to the extent permitted by law, be treated by **CHOP** as commercial and financial information obtained from a person and as privileged and confidential.

9.10. **Licensee** may request to pay some or all of the **CHOP Fees** (excluding earned royalties and sublicensing royalties) in the form of common stock, subject to mutual agreement between the **Parties** of the fair value of such common stock to be issued as consideration.

9.11. Payments made by **Licensee** to **CHOP** pursuant to this **Agreement** shall be delivered to the address set forth below or by wire transfer, in U.S. Dollars and reference CHOP ID: 0904-17 0932-17, 0933-17, and 1136-19 (unless otherwise stated on an invoice or specifically agreed by the Parties in writing):

The Children's Hospital of Philadelphia
Lock Box #1457

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P.O. Box 8500
Philadelphia, PA 19178-1457

If by wire transfer using the following electronic wire instructions:

Bank: Wells Fargo, N.A.
ABA 121000248
Account Number: 2000049262603
Wells Fargo Bank
One South Broad Street
Philadelphia, PA 19107

For international wires in, please include Swift Code:

Swift Code: WFBIUS6S

Branch/Office
Healthcare Financial Services
123 South Broad Street, 15th Floor
Y1379-158
Philadelphia, PA 19109

10. PERFORMANCE

10.1. **Licensee** shall use its reasonable best efforts to bring the **Licensed Products** or **Licensed Processes** to **Practical Application**. "Reasonable best efforts" for the purposes of this provision shallmean with respect to the efforts to be expended by Licensee regarding any objective required herein, the performance of obligations or tasks in a manner consistent with the reasonable commercial practices of companies in the biopharmaceutical industry seeking to accomplish such objective, including with respect to the research, development, manufacture and commercialization of Licensed Products or Licensed Processes, as applicable, such efforts consistent with the reasonable commercial practices of companies of comparable size and resources in the biopharmaceutical industry for a similar product at a similar research, development or commercialization stage and having similar market potential, profit potential and strategic value and includes adherence to the **Commercial Development Plan** at **Appendix D** (as may be amended in accordance with this Agreement) and performance of the **Milestones** at **Appendix C**. The efforts of a sublicensee shall be included in the efforts of **Licensee**.

10.2. Upon the **First Commercial Sale**, until the expiration of this **Agreement**, **Licensee** shall use its reasonable best efforts to make **Licensed Products** or **Licensed Processes** reasonably accessible to the United States public.

10.3. **CHOP** will make its personnel reasonably available to Licensee during normal business hours to transfer **CHOP Know How**.

11. INFRINGEMENT AND PATENT ENFORCEMENT

11.1. **CHOP** and **Licensee** agree to notify each other promptly of each infringement or possible infringement of the **Licensed Patent Rights** or **CHOP Co-Owned IP**, as well as any facts which may affect the validity, scope, or enforceability of the **Licensed Patent Rights** or **CHOP Co-Owned IP** of which either **Party** becomes aware.

11.2. Pursuant to this **Agreement** and the provisions of Chapter 29 of Title 35, United States Code, **Licensee** may (a) bring suit in its own name, at its own expense, and on its own behalf for infringement of the **Licensed Patent Rights**; (b) in any such suit, enjoin infringement and collect for its use, damages, profits, and awards of whatever nature recoverable for such infringement; and (c) settle any claim or suit for infringement of the **Licensed Patent Rights** provided, however, that **CHOP** shall have the first right to take such actions. If **Licensee** desires to initiate a suit for patent infringement, **Licensee** shall notify **CHOP** in writing. If **CHOP** does not notify **Licensee** of its intent to pursue legal action within thirty (30) days, **Licensee** will be free to initiate suit. **CHOP** shall have a continuing right to intervene in such suit. **Licensee** may not join **CHOP** as a party in a suit initiated by **Licensee** without **CHOP**'s prior written consent, unless such joinder is required by applicable law in order for **Licensee** to commence or maintain suit, in which case **CHOP** will cooperate with **Licensee** in being joined in such suit. Otherwise, **Licensee** shall take no action to compel **CHOP** to initiate or to join in any such suit for patent infringement. Should **CHOP** be made a **Party** to any such suit, **Licensee** shall reimburse **CHOP** for any costs, expenses, or fees, which **CHOP** incurs as a result of such action. In all cases, **Licensee** agrees to keep **CHOP** reasonably apprised of the status and progress of any litigation, but such obligation shall not require Licensee to waive any privilege or work product doctrine. Before **Licensee** commences an infringement action, **Licensee** shall notify **CHOP** and give consideration to the views of **CHOP** and to any potential effects of the litigation on the public health in deciding whether to bring suit.

11.3. In the event that a declaratory judgment action or post-grant proceeding alleging invalidity or non-infringement of any of the **Licensed Patent Rights** shall be brought against **CHOP** or **Licensee** or any of the **Licensed Patent Rights** or raised by way of counterclaim or affirmative defense in an infringement suit brought by **Licensee** under Paragraph 11.2, pursuant to this **Agreement** and the provisions of Chapter 29 of Title 35, United States Code or other statutes, **Licensee** may (a) defend the suit or proceeding in its own name, at its own expense, and on its own behalf for the **Licensed Patent Rights**; (b) in any such suit, seek to enjoin infringement and to collect for its use, damages, profits, and awards of whatever nature recoverable for such infringement; and (c) settle any claim or suit for declaratory judgment involving the **Licensed Patent Rights**, provided, however, that **CHOP** shall have the first right to take such actions and shall have a continuing right to intervene in such suit. If **CHOP** does not notify **Licensee** of its intent to respond to the legal action within a reasonable time, **Licensee** will be free to do so. **Licensee** may not join **CHOP** as a party in a suit initiated by **Licensee** without **CHOP**'s prior written consent, unless such joinder is required by applicable law in order for **Licensee** to commence or maintain suit, in which case **CHOP** will cooperate with **Licensee** in being joined in such suit. Otherwise, **Licensee** shall take no action to compel **CHOP** either to initiate or to join in any such declaratory judgment action. Should **CHOP** be made a **Party** to any such action of **Licensee**, **Licensee** shall reimburse **CHOP** for any costs,

expenses, or fees which **CHOP** incurs as a result of such action. If **Licensee** elects not to defend against such declaratory judgment action, **CHOP** at its option, may do so at its own expense. In all cases, **Licensee** agrees to keep **CHOP** reasonably apprised of the status and progress of any litigation, but such obligation shall not require **Licensee** to waive any privilege or work product doctrine. Before **Licensee** commences an infringement action, **Licensee** shall notify **CHOP** and give consideration to the views of **CHOP** and to any potential effects of the litigation on the public health in deciding whether to bring suit.

11.4. In any action under Paragraphs 11.2 or 11.3, the expenses including costs, fees, attorney fees, and disbursements, shall be paid by **Licensee**. Up to fifty percent (50%) of such expenses may be credited against the royalties payable to **CHOP** under Paragraph 6.3 under the **Licensed Patent Rights** or **CHOP Co-Owned IP** in the country in which such an action is filed. In the event that fifty percent (50%) of such expenses exceed the amount of royalties payable by **Licensee** in any calendar year, the expenses in excess may be carried over as a credit on the same basis into succeeding calendar years. A credit against litigation expenses, however, may not reduce the royalties due in any calendar year to less than the minimum annual royalty. Any recovery made by **Licensee**, through court judgment or settlement, first shall be applied to reimburse **CHOP** for royalties withheld as a credit against litigation expenses and then to reimburse **Licensee** for its litigation expense. Any remaining recoveries shall be considered **Net Sales**

11.5. **CHOP** shall cooperate fully with **Licensee** in connection with any action under Paragraphs 11.2 or 11.3. **CHOP** agrees promptly to provide access to all necessary documents and to render reasonable assistance in response to a request by **Licensee**.

11.6. Pursuant to this **Agreement** and the provisions of Chapter 29 of Title 35, United States Code, **Licensee** may (a) bring suit in its own name, at its own expense, and on its own behalf for infringement of the **CHOP-Co-Owned IP**; (b) in any such suit, enjoin infringement and collect for its use, damages, profits, and awards of whatever nature recoverable for such infringement; and (c) settle any claim or suit for infringement of the **CHOP-Co-Owned IP** provided, however, that **CHOP** shall have the first right to take such actions. If **Licensee** desires to initiate a suit for patent infringement, **Licensee** shall notify **CHOP** in writing. If **CHOP** does not notify **Licensee** of its intent to pursue legal action within thirty (30)days, **Licensee** will be free to initiate suit. **CHOP** shall have a continuing right to intervene in such suit. **Licensee** may not join **CHOP** or Spark Therapeutics as a party in a suit initiated by **Licensee** without **CHOP** or Spark Therapeutic's respective prior written consent unless such joinder is required by applicable law in order for **Licensee** to commence or maintain suit, in which case **CHOP** will cooperate with **Licensee** in being joined in such suit. Otherwise, **Licensee** shall take no action to compel **CHOP** or Spark Therapeutics to initiate or to join in any such suit for patent infringement. Should **CHOP** be made a **Party** to any such suit, **Licensee** shall reimburse **CHOP** for any costs, expenses, or fees, which **CHOP** incurs as a result of such action. In all cases, **Licensee** agrees to keep **CHOP** reasonably apprised of the status and progress of any litigation, but such obligation shall not require **Licensee** to waive any privilege or work product doctrine. Before **Licensee** commences an infringement action, **Licensee** shall notify **CHOP** and give consideration to the views of **CHOP** and to

any potential effects of the litigation on the public health in deciding whether to bring suit.

11.7. In the event that a declaratory judgment action or post-grant proceeding alleging invalidity or non-infringement of any of the **CHOP-Co-Owned IP** shall be brought against **CHOP** or **Licensee** or any of the **CHOP-Co-Owned IP** or raised by way of counterclaim or affirmative defense in an infringement suit brought by **Licensee** under Paragraph 11.2, pursuant to this **Agreement** and the provisions of Chapter 29 of Title 35, United States Code or other statutes, **Licensee** may (a) defend the suit or proceeding in its own name, at its own expense, and on its own behalf for the **CHOP-Co-Owned IP**; (b) in any such suit, seek to enjoin infringement and to collect for its use, damages, profits, and awards of whatever nature recoverable for such infringement; and (c) settle any claim or suit for declaratory judgment involving the **CHOP-Co-Owned IP**, provided, however, that **CHOP** shall have the first right to take such actions and shall have a continuing right to intervene in such suit. Licensee may not join CHOP or Spark Therapeutics as a party in a suit initiated by Licensee without CHOP or Spark Therapeutic's prior written consent, unless such joinder is required by applicable law in order for **Licensee** to commence or maintain suit, in which case **CHOP** will cooperate with **Licensee** in being joined in such suit. Otherwise, **Licensee** shall take no action to compel **CHOP** or Spark Therapeutics to initiate or to join in any such suit for patent infringement. Should **CHOP** be made a **Party** to any such action of **Licensee**, **Licensee** shall reimburse **CHOP** for any costs, expenses, or fees which **CHOP** incurs as a result of such action. If **Licensee** elects not to defend against such declaratory judgment action, **CHOP** at its option, may do so at its own expense. In all cases, **Licensee** agrees to keep **CHOP** reasonably apprised of the status and progress of any litigation, but such obligation shall not require **Licensee** to waive any privilege or work product doctrine. Before **Licensee** commences an infringement action, **Licensee** shall notify **CHOP** and give consideration to the views of **CHOP** and to any potential effects of the litigation on the public health in deciding whether to bring suit.

11.8. In any action under Paragraphs 11.2 or 11.3, the expenses including costs, fees, attorney fees, and disbursements, shall be paid by **Licensee**. Up to fifty percent (50%) of such expenses may be credited against the royalties payable to **CHOP** under Paragraph 6.3 under the **CHOP-Co-Owned IP** in the country in which such an action is filed. In the event that fifty percent (50%) of such expenses exceed the amount of royalties payable by **Licensee** in any calendar year, the expenses in excess may be carried over as a credit on the same basis into succeeding calendar years. A credit against litigation expenses, however, may not reduce the royalties due in any calendar year to less than the minimum annual royalty. Any recovery made by **Licensee**, through court judgment or settlement, first shall be applied to reimburse **CHOP** for royalties withheld as a credit against litigation expenses and then to reimburse **Licensee** for its litigation expense. Any remaining recoveries shall be considered **Net Sales**

12. NEGATION OF WARRANTIES AND INDEMNIFICATION

12.1. **CHOP** offers no warranties other than those specified in Article 1.

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12.2. **CHOP** does not warrant the validity of the **Licensed Patent Rights CHOP Co-Owned IP, Licensed Product(s), Licensed Processes,** or **CHOP Know-How** and makes no representations whatsoever with regard to the scope of the **Licensed Patent Rights, CHOP Co-Owned IP,** or **CHOP Know-How**, or that the **Licensed Patent Rights, CHOP Co-Owned IP, Licensed Product(s), Licensed Processes** or **CHOP Know-How** may be exploited without infringing other patents or other intellectual property rights of third parties.

12.3. **CHOP** MAKES NO WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF ANY SUBJECT MATTER DEFINED BY THE CLAIMS OF THE **LICENSED PATENT RIGHTS OR CHOP CO-OWNED IP**. LICENSEE ACCEPTS **LICENSED PATENT RIGHTS, CHOP'S RIGHTS IN THE CHOP CO-OWNED IP,** AND **CHOP KNOW-HOW** "AS IS" AND **CHOP** DOES NOT OFFER ANY GUARANTEE OF ANY KIND.

12.4. **CHOP** does not represent that it will commence legal actions against **Third Parties** infringing the **Licensed Patent Rights** or **CHOP Co-Owned IP** other than as provided in Article 11.

12.5. **Licensee** hereby agrees to indemnify, defend and hold **CHOP** and its employees, directors, agents and consultants, and their respective successors, heirs and assigns and representatives ("**CHOP Indemnitees**") harmless from and against all claims, liability, threatened claims, damages, expenses (including reasonable attorneys' fees), suits, proceedings, losses or judgments, whether for money or equitable relief, of any kind, including death, personal injury, illness, product liability or property damage or the failure to comply with applicable law (collectively, "**Losses**"), arising from any **Third Party** claim due to (i) the development, commercialization (including promotion, advertising, offering for sale, sale or other disposition), transfer, importation or exportation, manufacture, labeling, handling or storage, or use of, or exposure to, any **Licensed Product** or **Licensed Processes** by or for **Licensee** or any of its sublicensees, subcontractors, agents and consultants; or (ii) **Licensee's** and its sublicensees' use or practice of **Licensed Patent Rights, CHOP Co-Owned IP**, and **CHOP Know-How**; or (iii) any material breach of any obligation, representation or warranty of **Licensee** hereunder; or (iv) **Licensee's** and its sublicensees' gross negligence, recklessness, or willful misconduct, except, in each case, to the extent that such Losses arise from the gross negligence, recklessness or willful misconduct of any **CHOP Indemnitees**.

12.6. Indemnification Procedure. As a condition to the right to receive indemnification under this Article 12, **CHOP** shall: (i) promptly notify Licensee as soon as it becomes aware of a claim or suit for which indemnification may be sought pursuant hereto (it being understood and agreed, however, that the failure by **CHOP** to give such notice shall not relieve Licensee of its indemnification obligation under this Agreement except and only to the extent that Licensee is actually prejudiced as a result of such failure to give notice); (ii) reasonably cooperate, and cause the individual **CHOP** Indemnitees seeking indemnity to reasonably cooperate, with Licensee in the defense, settlement or compromise of such claim or suit; and (iii) permit Licensee to control the defense, settlement or compromise of such claim or

suit, including the right to select defense counsel. In no event, however, may Licensee compromise or settle any claim or suit in a manner which (a) admits fault or negligence on the part of **CHOP** or any other **CHOP** Indemnitee or (b) commits **CHOP** or any other **CHOP** Indemnitee to take, or forbear to take, any action, without the prior written consent of **CHOP**.

12.7. EXCLUSION OF DAMAGES; LIMITATIONS OF LIABILITY. EXCEPT WITH RESPECT TO THE INDEMNIFICATION OBLIGATIONS OF LICENSEE UNDER PARAGRAPH 12.5 OR WITH RESPECT TO THE CONFIDENTIALITY OBLIGATIONS OF BOTH PARTIES, NEITHER **PARTY** SHALL BE LIABLE TO THE OTHER **PARTY** FOR SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE, OR CONSEQUENTIAL DAMAGES ARISING OUT OF THIS **AGREEMENT**.

The foregoing exclusion of damages:

(i) applies even if a **Party** had or should have had actual or constructive knowledge of the possibility of such damages,

(ii) is a fundamental element of the basis of the bargain between the **Parties**, and this **Agreement** would not be entered into without such limitations and exclusions, and

(iii) shall apply whether an action is based on breach of contract, breach of warranty, tort (including negligence), product liability, strict liability or otherwise, and notwithstanding any failure of essential purpose of any limited remedy herein.

The foregoing exclusion of damages is intended to apply even if there is a total and fundamental breach of this **Agreement**. The essential purpose of the exclusion of damages clause is to limit the **Parties'** respective liabilities to each other hereunder.

The **Parties** acknowledge and agree that the disclaimers, exclusions, and limitations of liability set forth in this Article 12 form an essential basis of this **Agreement**, and that, absent any of such disclaimers, exclusions or limitations of liability, the terms of this **Agreement**, including the economic terms, would be substantially different.

Each **Party** shall comply with all applicable laws and regulations relative to its obligations hereunder.

13. TERM, TERMINATION, AND MODIFICATION OF RIGHTS

13.1. This **Agreement** is effective as of the Effective Date and shall extend until the expiration of the **Royalty Term** unless sooner terminated as provided in this Article 13.

13.2. In the event that **Licensee** is in default in the performance of any material obligations under this **Agreement**, including but not limited to the obligations listed in Article 13.5, and if the default has not been remedied within ninety (90) days after the date of notice in writing of such default, **CHOP** may terminate this **Agreement** by written notice.

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13.3. In the event that **Licensee** becomes insolvent, files a petition in bankruptcy, has such a petition filed against it, determines to file a petition in bankruptcy, or receives notice of a **Third Party's** intention to file an involuntary petition in bankruptcy, **Licensee** shall immediately notify **CHOP** in writing.

13.4. **Licensee** shall have a unilateral right to terminate, without cause,this **Agreement** and/or any licenses in any country by giving **CHOP** sixty (60) days notice to that effect.

13.5. **CHOP** shall specifically have the right to terminate or modify, at its option, this **Agreement**, if **CHOP** reasonably determines that the **Licensee**: (1) is not executing the **Commercial Development Plan** submitted with its request for a license and the **Licensee** cannot otherwise demonstrate that the **Licensee** has taken, or can be expected to take within a reasonable time, effective steps to achieve **Practical Application** of the **Licensed Productsor Licensed Processes**; (2) has not achieved the **Milestones** as may be modified under Paragraph 9.2; (3) has willfully made a false statement of, or willfully omitted, a material fact in the license application or in any report required by the license **Agreement**; (4) has committed a material breach of a covenant or **Agreement** contained in the license; (5) is not keeping **Licensed Productsor Licensed Processes** reasonably available to the public after commercial use commences; (6) cannot reasonably satisfy unmet health and safety needs; or (7) cannot reasonably justify a failure to comply with the domestic production requirement of Paragraph 5.2 unless waived. In making this determination, **CHOP** will take into account the normal course of such commercial development programs conducted with sound and reasonable business practices and judgment and the annual reports submitted by **Licensee** under Paragraph 9.2. Prior to invoking this right, **CHOP** shall give written notice to **Licensee** concerns as to the previous items (1) to (7) and if Licensee fails to initiate reasonable corrective action, **CHOP** may terminate this **Agreement**.

13.6. When the public health and safety so require, and after written notice to **Licensee** providing **Licensee** a sixty (60) day opportunity to respond, **CHOP** shall have the right to require **Licensee** to grant **Sublicenses** to responsible applicants, on reasonable terms, in any **Licensed Fields of Use** under the **Licensed Patent Rights** or **CHOP's** rights in the **CHOP Co-owned IP**, unless **Licensee** can reasonably demonstrate that the granting of the sublicense would not materially increase the availability to the public of the subject matter of the **Licensed Patent Rights** or **CHOP Co-Owned IP**. **CHOP** will not require the granting of a sublicense unless the responsible applicant has first negotiated in good faith with **Licensee**.

13.7. **CHOP** reserves the right according to 35 U.S.C. § 209(D)(3) (c) to terminate or modify this **Agreement** if it is determined that such action is necessary to meet requirements for public use specified by federal regulations issued after the date of the license and such requirements are not reasonably satisfied by **Licensee**.

13.8. Within thirty (30) days of receipt of written notice of **CHOP**'s unilateral decision to modify or terminate this **Agreement** under Paragraph 13.7, **Licensee** may, consistent with the provisions of 37 C.F.R. § 404.11, appeal the decision by written submission to the designated **CHOP** official. The decision of the designated **CHOP** official

shall be the final agency decision. **Licensee** may thereafter exercise any and all administrative or judicial remedies that may be available.

13.9. Within ninety (90) days of termination of this **Agreement** under this Article 13 or expiration under Paragraph 13.1, a final report shall be submitted by **Licensee**. Any royalty payments, including those related to patent expense, due to **CHOP** shall become immediately due and payable upon termination or expiration. If terminated under this Article 13, sublicensees may elect to convert their sublicenses to direct licenses with **CHOP** pursuant to Paragraph 4.3.

14. CONFIDENTIAL INFORMATION AND PUBLICITY

14.1 Except as expressly provided herein, each of the **Parties** agrees that for the period from the **Effective Date** to three (3) years after the earlier of expiration or termination of this **Agreement**, a **Party** (the "**Receiving Party**") receiving **Confidential Information** of the other **Party** (the "**Disclosing Party**") will (1) not disclose such **Confidential Information** to any **Third Party** without the prior written consent of the **Disclosing Party**, except for disclosures expressly permitted below, and (2) not use such **Confidential Information** for any purpose except those licensed or otherwise authorized or permitted by this **Agreement**.

The **Receiving Party** may disclose **Confidential Information** belonging to the **Disclosing Party** to the extent (and only to the extent) such disclosure is reasonably necessary in the following instances:

(i) by either **Party** in order to comply with applicable laws (including any securities laws or regulation or rules of a securities exchange) or with a legal or administrative proceeding;

(ii) by either **Party**, in connection with prosecuting or defending litigation, making regulatory filings, and prosecuting Licensed Patent Rights under this **Agreement**;

(iii) by and among **Licensee** and potential and future sublicensees, permitted acquirers or assignees, subcontractors, investment bankers, investors, lenders, and their and each of **Licensee's** respective directors, employees, contractors and agents; and

(iv) by either **Party**, permitted acquirers or assignees, subcontractors, attorneys, investment bankers, investors (including royalty purchasers), lenders, and their and each of such **Party** respective directors, employees, contractors and agents, provided that (A) with respect to Article 14.1(i) and (ii), where reasonably possible, the **Receiving Party** will notify the **Disclosing Party** of the **Receiving Party's** intent to make any disclosure pursuant thereto sufficiently prior to making such disclosure so as to allow the **Disclosing Party** adequate time to take whatever action it may deem appropriate to protect the confidentiality of the information to be disclosed, and (B) with respect to Articles 14.1(iii) and (iv), each of those named people and entities must be bound prior to disclosure by confidentiality and non-use restrictions at least as restrictive as those contained in this **Agreement** (other than investment bankers, investors and lenders, who must be bound prior to disclosure by commercially reasonable obligations of confidentiality and attorneys bound by professional

obligations of confidentiality). Further, with respect to Article 14.1(i)], in the event either **Party** intends to make a disclosure pursuant thereto, the other **Party** will have a reasonable time period to review and comment on the proposed disclosure or filing that relates to this **Agreement** (including the right to request redaction of material terms to the extent permitted by any applicable laws), and the **Party** intending to make such disclosure will consider in good faith any reasonable comments thereon provided by the other **Party**.

14.2 This **Agreement** supersedes any other confidentiality agreements between the **Parties**, provided that all **Confidential Information** disclosed or received by the **Parties** under any preceding confidentiality agreements will be deemed **Confidential Information** hereunder and will be subject to the terms and conditions of this **Agreement**.

15. GENERAL PROVISIONS

15.1 Neither **Party** may waive or release any of its rights or interests in this **Agreement** except in writing. The failure of a **Party** to assert a right hereunder or to insist upon compliance with any term or condition of this **Agreement** shall not constitute a waiver of that right by that **Party** or excuse a similar subsequent failure to perform any such term or condition by the other **Party**.

15.2 This **Agreement** constitutes the entire **Agreement** between the **Parties** relating to the subject matter of the **Licensed Patent Rights** and **CHOP Co-Owned IP**, and all prior negotiations, representations, **Agreements**, and understandings are merged into, extinguished by, and completely expressed by this **Agreement**.

15.3 The provisions of this **Agreement** are severable, and in the event that any provision of this **Agreement** shall be determined to be invalid or unenforceable under any controlling body of law such determination shall not in any way affect the validity or enforceability of the remaining provisions of this **Agreement**.

15.4 If either **Party** desires a modification to this **Agreement**, the **Parties** shall, upon reasonable notice of the proposed modification by the **Party** desiring the change, confer in good faith to determine the desirability of such modification. No modification will be effective until a written amendment is signed by the signatories to this **Agreement** or their designees.

15.5 All disputes between the **Parties** shall be governed by the laws of New York not withstanding any of that state's laws to the contrary, and without regard to principles of conflicts of laws; provided, however, the foregoing shall not apply to disputes arising out of or relating to intellectual property which shall be governed by applicable federal laws and/or laws of New York (without regard for principles of conflicts of laws) as they apply to the given situation The **Parties** further expressly agree that the exclusive venue for the resolution of any such disputes (including intellectual property shall be the state and federal courts located in New York and that such courts shall have exclusive jurisdiction. The **Parties** hereby submit themselves to venue in New York and to the exclusive jurisdiction of such courts for such purposes. EACH **PARTY** HEREBY IRREVOCABLY AND UNCONDITIONALLY WAIVES, TO THE FULLEST EXTENT IT MAY

LEGALLY AND EFFECTIVELY DO SO, TRIAL BY JURY IN ANY SUIT, ACTION OR PROCEEDING ARISING HEREUNDER AND ANY CLAIM OF INCONVENIENT FORUM OF ANY COURT IN NEW YORK.

15.6 All notices required or permitted by this **Agreement** shall be given by prepaid, first class, registered or certified mail properly addressed to the other **Party** at the address designated on the following signature page, or to such other address as may be designated in writing by such other **Party**, and shall be effective as of the date of the postmark of such notice.

15.7 **Licensee** may transfer or assign its rights and obligations under this **Agreement**, without consent if such assigment is a **Qualified Assignment**, , to an Affiliate or a successor to all or substantially all of its business or assets relating to this Agreement, whether by sale, merger, operation of law or otherwise, provided that, in the event of such sale or merger, such assignment is a "Qualified Assignment" and that Licensee notifies **CHOP** within ten (10) days of any **Qualified Assignment**, and Licensee provides **CHOP** a copy of such assignment (subject to redaction of any financial or confidential parts of the assignment document or other parts of the assignment document that relate to assets or parts of the business that are not relevant to this **Agreement**).

For the purposes of this Agreement, a "**Qualified Assignment**" means any assignment that:

(a) is made in compliance with applicable laws;
(b) includes the assignee's written acknowledgement of and written agreement to all of the **Licensee**'s obligations under the **Agreement**;
(c) is made to an assignee that is, and will be after giving effect to the relevant assignment, Solvent;
(d) is made to an assignee that is not subject at the time of such assignment to any order, decree or petition providing for (i) the winding-up or liquidation of such person, (ii) the appointment of a receiver over the whole or part of the assets of such person or (iii) the bankruptcy or administration of such person;
(e) is not a voidable fraudulent conveyance;
(f) is made to an assignee that is at the time of such assignment not debarred under 21 U.S.C. §30 or under investigation or threatened to be debarred under 21 U.S.C. §30; and
(g) will not cause a material increase in taxes, costs or expenses to **CHOP** other than as a result of increased income to **CHOP** (unless the **Licensee** or the assignee has agreed to compensate **CHOP** for the same).

15.7.1 For purposes of this Paragraph 15.7, "**Solvent**" means, with respect to any person as on any date of determination, that as of such date, (i) the value of the assets of such person is greater than the total amount of liabilities (including contingent and unliquidated liabilities) of such person, (ii) such person is able to pay all liabilities of such person as such liabilities mature and (iii) such person does not have unreasonably small capital (taking into account such person's obligations hereunder). In computing the amount of contingent or unliquidated liabilities at any time, such liabilities shall be computed at the amount that, in light of all the facts and circumstances existing at such time, represent the amount that can reasonably be expected to become an actual or matured liability.

15.7.2 Except as provided herein, the **Parties** agree that their rights and obligations under this **Agreement** may not be transferred or assigned without the prior written consent of the other **Party** hereto, which consent may be withheld in such other **Party's** sole discretion.

15.7.3 Notwithstanding anything to the contrary in this Paragraph 15.7 or elsewhere in this Agreement, **CHOP** may sell, transfer or assign its rights to any **Third Party** to receive payments under this **Agreement**, and **CHOP** may disclose **Confidential Information** of **Licensee** to one or more **Third Parties** in connection with any such assignment to enable the **Third Party(ies)** to evaluate and monitor any such purchase.

15.7.4 Any attempted assignment, delegation or transfer in violation of this Paragraph 15.7 will be void. Any permitted assignee will assume all assigned obligations of its assignor under this **Agreement**. The terms and conditions of this **Agreement** will inure to the benefit of, and be binding upon, the legal representatives, successors and permitted assigns of the **Parties**.

15.8 **Licensee** agrees in its use of any **CHOP** supplied materials to comply with all applicable statutes, regulations, and guidelines, including Public Health Service and National Institutes of Health regulations and guidelines. **Licensee** agrees not to use the materials for research involving human subjects or clinical trials in the United States without complying with 21 C.F.R. § Part 50 and 45 C.F.R. § Part 46. **Licensee** agrees not to use the materials for research involving human subjects or clinical trials outside of the United States without notifying **CHOP**, in writing, of such research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to **CHOP** research involving human subjects or clinical trials outside of the United States shall be given no later than sixty (60) days prior to commencement of such research or trials.

15.9 **Licensee** acknowledges that it is subject to and agrees to abide by the United States laws and regulations (including the Export Administration Act of 1979 and Arms Export Control Act) controlling the export of technical data, computer software, laboratory prototypes, biological material, and other commodities. The transfer of such items may require a license from the cognizant Agency of the U.S. **Government** or written assurances by **Licensee** that it shall not export such items to certain foreign countries without prior approval of such agency. **CHOP** neither represents that a license is not required or that, if required, it shall be issued.

15.10 **Licensee** agrees to mark the **Licensed Products** or their packaging sold in the United States with all applicable U.S. patent numbers and similarly to indicate "Patent Pending" status. All **Licensed Products** manufactured in, shipped to, or sold in other countries shall be marked in such a manner as to preserve **CHOP** patent rights in such countries.

15.11 By entering into this **Agreement**, **CHOP** does not directly or indirectly endorse any product or service provided, or to be provided, by **Licensee** whether directly or indirectly related to this **Agreement**. **Licensee** shall not state or imply that this

Agreement is an endorsement by **CHOP** or their employees in any advertising, promotional, or sales literature without the prior written consent of **CHOP**.

15.12 The **Parties** agree to attempt to settle amicably any controversy or claim arising under this **Agreement** or a breach of this **Agreement**, except for appeals of modifications or termination decisions provided for in Article 13. Any dispute that is not resolved between the Parties shall first be escalated to the Chief Executive Officer of Licensee and Chief Scientific Officer of **CHOP**, or their designees (collectively, the "**Executive Officers**"). If the Executive Officers cannot reach a resolution within thirty (30) days after escalation, any Party may exercise any administrative or judicial remedies that may be available.

15.13 Neither **Party** shall make use of the name, abbreviation, nickname, logo, trademark, trade dress, symbol or other unique term, symbol or identifying mark of the other **Party** without prior written consent of the other **Party**.

15.14 Nothing relating to the grant of a license, nor the grant itself, shall be construed to confer upon any person any immunity from or defenses under the antitrust laws or from a charge of patent misuse, and the acquisition and use of rights pursuant to 37 C.F.R. § Part 404 shall not be immunized from the operation of state or Federal law by reason of the source of the grant.

15.15 This Agreement may be executed in two or more counterparts, all of which shall constitute one and the same legal instrument, and delivery of an executed copy of this Agreement by any Party via electronic transmission will be as effective as delivery of a manually executed copy of this Agreement.

15.16 Article 2 and Paragraphs 3.4, 4.3, 6.6–6.9, 8.1, 9.6-9.8, 9.11, 12.1-12.5, 12.7, 13.5, 13.7–9, 14.1, 15.5-7, and 15.14 of this **Agreement** shall survive termination of this **Agreement.**

For **CHOP**:

DocuSigned by:
0234C064FF32477...

11/15/2019

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Signature of Authorized **CHOP** Official Date
Printed Name: Zev Sunleaf
Title: VP, Office of Technology Transfer, Innovation, and Research Contracts

Mailing Address for Notices:
The Children's Hospital of Philadelphia
Robert's Building for Pediatric Research
2716 South Street
Philadelphia, PA 19146
Attention: VP, Office of Technology Transfer, Innovation, and Research Contracts

For **Licensee** (Upon, information and belief, the undersigned expressly certifies or affirms that the contents of any statements of **Licensee** made or referred to in this document are truthful and accurate.):
by:

DocuSigned by:
Jason Slakter
08E686FF5B7641B...

11/15/2019

Signature of Authorized Orphion Official Date
Printed Name: Jason S. Slakter, M.D.
Title: Chief Executive Officer

Mailing Address for Notices:
57 Meadow Woods Road
Great Neck, NY 11020

APPENDIX A -- Patent(s) or Patent Application(s):

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Internal ID	Country	Serial No.	Title
0933PCT	PCT	PCT/US2017/059986	Gene Transfer Compositions, Methods and Uses for Treating Neurodegenerative Diseases
0933P	US Provisional	62/418,033	Gene Transfer Compositions, Methods and Uses for Treating Neurodegenerative Diseases
0904PCT	PCT	PCT/US2018/032454	Sulfamidase (SGSH) Variants, Vectors, Compositions and Methods and Uses for Treating Mucopolysaccharidosis Type IIIA (MPS IIIA)
0904P	US Provisional	62/505,423	Heparan N-Sulfatase (HNS) Variants, Vectors Compositions and Methods and Uses for Treating Mucopolysaccharidosis Type IIIA (MPS IIIA)
1136P	US Provisional	62/831,067	Treatment of Lysosomal Storage Disease in the Eye Through Subretinal Administration of AAVs Expressing TPP1
0933MX	Nationalized PCT	MX/a/2019/005266	Gene Transfer Compositions, Methods and Uses for Treating Neurodegenerative Diseases
0933IN	Nationalized PCT	201927021893	Gene Transfer Compositions, Methods and Uses for Treating Neurodegenerative Diseases
0933JP	Nationalized PCT	2019-522377	Gene Transfer Compositions, Methods and Uses for Treating Neurodegenerative Diseases
0933EP	Nationalized PCT	17867272.1	Gene Transfer Compositions, Methods and Uses for Treating Neurodegenerative Diseases
0933BR	Nationalized PCT	112019009074-6	Gene Transfer Compositions, Methods and Uses for Treating Neurodegenerative Diseases
0933RU	Nationalized PCT	2019117062	Gene Transfer Compositions, Methods and Uses for Treating Neurodegenerative Diseases
0933CA	Nationalized PCT	3,041,548	Gene Transfer Compositions, Methods and Uses for Treating Neurodegenerative Diseases
0933US	Nationalized PCT	16/344,298	Gene Transfer Compositions, Methods and Uses for Treating Neurodegenerative Diseases
0933AU	Nationalized PCT	2017355502	Gene Transfer Compositions, Methods and Uses for Treating Neurodegenerative Diseases
0933CN	Nationalized PCT	201780067919.4	Gene Transfer Compositions, Methods and Uses for Treating Neurodegenerative Diseases

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APPENDIX B -- Considerations:

Licensee agrees to pay to **CHOP** a noncreditable, nonrefundable license issue fee according to Article 6 in the amount of: $25,000

Licensee agrees to pay to **CHOP** a creditable, nonrefundable minimum annual royalty according to Article 6 in the amount of: $25,000

Licensee agrees to pay **CHOP** earned royalties according to Article 6 on **Net Sales** as follows:

Earned Royalty will be paid	**Percent (%)**
Up to $50M in **Net Sales** in the **Territory**	1.70%
$50M-$100M in **Net Sales** in the **Territory**	2.4%
Over $100M in **Net Sales** in the **Territory**	3.05%

Upon achievement of each **Milestone Event** in each of the following **Licensed Products** or **Licensed Process, Licensee** agrees to pay **CHOP** one-time milestones payments according to Article 6 within 30 days of such achievement as follows:

Milestone Event	**Milestone Payment**
Clinical Proof of Concept in Phase 1/2 Trial for first **Licensed Product** or services rendered under a **Licensed Process** (TPP1 Retinal Program)	$50,000
First Commercial Sale in the first country for first **Licensed Product** or services rendered under a **Licensed Process** (TPP1 Retinal Program)	$150,000
Clinical Proof of Concept in Phase 1/2 Trial for first **Licensed Product** or services rendered under a **Licensed Process** (TPP1 CNS Program)	$50,000
First Commercial Sale in the first country for first **Licensed Product** or services rendered under a **Licensed Process** (TPP1 CNS Program)	$150,000
Clinical Proof of Concept in Phase 1/2 Trial for first **Licensed Product** or services rendered under a **Licensed Process** (MPSIIIa Program)	$50,000
First Commercial Sale in the first country for first **Licensed Product** or services rendered under a **Licensed Process** (MPS IIIa Program)	$150,000

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Licensee agrees to pay **CHOP** sublicensing royalties according to Article 6 in the form such **Sublicense Income** is received by **Licensee** as follows:

Sublicense entered into prior to clinical proof of concept: 15% of **Sublicense Income**.

Sublicense entered into after clinical proof of concept but prior to FDA approval: 10% of **Sublicense Income**.

Sublicense entered into after FDA approval: 5% of **Sublicense Income**.

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APPENDIX C -- Milestones:

Licensee agrees to the following **Milestones** for its performance under this **Agreement** and, with ten (10) days of achieving a **Milestone**, shall notify **CHOP** that the **Milestone** has been achieved:

Milestone Event	**Milestone Event Achievement Date**
TPP1 Retinal Program IND Filing	March 2021
TPP1 Retinal Program Clinical Trial Initiation	June 2021
MPS IIIa Program In vivo Proof of Concept	February 2021
TPPI CNS Program Initial In vitro/In vivo Data	March 2021
MPSIIIa Program IND Filing	March 2022

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APPENDIX D -- Commercial Development Plan:

The company will conduct the steps necessary to move each of the technologies forward to commercialization in the most expeditious manner possible using efforts and resources that a company similar financially and scientifically to Licensee would devote to a product at a similar stage in its lifecycle to the Licensed Product, having similar market potential, profit potential, safety, efficacy, clinical success, stage, or strategic value and considering strategic legal, regulatory, and patent issues of the product, based on conditions then prevailing taking into account issues of safety and efficacy, product profile, the proprietary position, the then current competitive environment and the likely timing of market entry, the regulatory environment and status of such product, and other relevant scientific, technical and commercial factors. The goal is to demonstrate that each product demonstrates safety and efficacy as required for regulatory approval. Key milestone dates are indicated.

TPP1 Retinal Program

- Natural history study to provide data for clinical trial
- IND-enabling GLP toxicology study
- FDA pre-IND meeting
- Study design and protocol preparation
- Submit IND – **March 2021**
- Clinical trial initiation - **June 2021**
- NDA/BLA for approval and commercialization

MPS IIIa Program

- In vivo studies – **February 2021**
- CMC development
- IND-enabling study(ies)
- FDA pre-IND meeting Study design and protocol preparation
- IND-enabling GLP study(ies)
- Submit IND – **March 2022**
- Clinical trial(s)
- NDA/BLA for approval and commercialization

TPP1 CNS Program

- In vitro development of therapeutic construct
- Initial POC testing in vitro/in vivo – **March 2021**
- In vivo biodistribution/safety studies
- CMC development
- IND-enabling study(ies)
- FDA pre-IND meeting
- Study design and protocol preparation
- Submit IND
- Clinical trial(s)
- NDA/BLA for approval and commercialization

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APPENDIX E – CHOP Co-Owned IP

Internal ID	Country	Serial No.	Title
0932P	United States	62/383,274	METHODS AND VECTORS FOR TREATING CNS DISORDERS
0932PCT	WIPO	PCT/US17/49959	METHODS AND VECTORS FOR TREATING CNS DISORDERS
0932US	United States	16/329,697	METHODS AND VECTORS FOR TREATING CNS DISORDERS
0932JP	Japan	2019-512292	METHODS AND VECTORS FOR TREATING CNS DISORDERS
0932CN	China	201780067677.9	METHODS AND VECTORS FOR TREATING CNS DISORDERS
0932CA	Canada	3,035,628	METHODS AND VECTORS FOR TREATING CNS DISORDERS
0932MX	Mexico	MX/a/2019/002518	METHODS AND VECTORS FOR TREATING CNS DISORDERS
0932BR	Brazil	BR 112019004353-5	METHODS AND VECTORS FOR TREATING CNS DISORDERS
0932EP	Europe	17847658.6	METHODS AND VECTORS FOR TREATING CNS DISORDERS
0932AU	Australia	2017318717	METHODS AND VECTORS FOR TREATING CNS DISORDERS

AMENDMENT NO. 1 TO LICENSE AGREEMENT

This Amendment No. 1 (hereinafter "**Amendment**"), is made and entered into as of May 5, 2020, (the "**Amendment Date**") by and between The Children's Hospital of Philadelphia, a non-profit entity organized and existing under the laws of Pennsylvania and having a principal place of business at 3401 Civic Center Boulevard, Philadelphia, PA 19104 ("**CHOP**"), and Orphion Therapeutics, a for-profit organization having a principal place of business at 57 Meadow Woods Road, Great Neck, NY 11020 ("**Licensee**"). CHOP and Licensee are sometimes referred to in this Amendment individually as a "**Party**" and collectively as the "**Parties**."

WHEREAS, CHOP and Licensee are Parties to that certain License Agreement dated October 28, 2019 (the "**Agreement**"); and

WHEREAS, CHOP and **Licensee** would like to amend the Agreement to extend dates of certain payments due from Licensee.

NOW, THEREFORE, in consideration of the foregoing premises and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties mutually agree as follows:

1. **Amendment of Section 6 (CONSIDERATION).**

(a) Amendment of Section 6.1. Effective as of the Amendment Date, Section 6.1 of the Agreement is hereby amended and restated to read in its entirety as follows:

> "During the Royalty Term, Licensee agrees to pay to CHOP a noncreditable, nonrefundable license issue fee as set forth in Appendix B on the earlier of thirty (30) days post Financing or on September 30, 2020. For clarification, "Financing" means investment of at least $1,000,000."

2. **Amendment of Section 7 (PATENT FILING, PROSECUTION, AND MAINTENANCE).**

(a) Amendment of Section 7.4. Effective as of the Amendment Date, Section 7.4 of the Agreement is hereby amended and restated to read in its entirety as follows:

> "With regard to expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the Licensed Patent Rights incurred by CHOP prior to the Effective Date of this Agreement, Licensee shall pay to CHOP an amount equivalent to such patent expenses previously incurred by CHOP according to the following schedule: Licensee shall pay to CHOP $52,000 within thirty (30) days of the Effective Date and Licensee shall pay to CHOP $65,409.11 on the earlier of thirty (30) days post Financing or on September 30th 2020. For clarification, "Financing" means investment of at least $1,000,000."

(b) Amendment of Section 7.5. Effective as of the Amendment Date, Section 7.5 of the Agreement is hereby amended and restated to read in its entirety as follows:

"With regard to expenses associated with the preparation, filing, prosecution, and maintenance of CHOP Co-Owned IP incurred by CHOP prior to June 30, 2020, Licensee shall pay to CHOP, on the earlier of thirty (30) days post Financing or on September 30, 2020, an amount equivalent to such previously incurred expenses by CHOP. With regard to expenses associated with the preparation, filing, prosecution, and maintenance of CHOP Co-Owned IP incurred by CHOP on or after June 30, 2020, Licensee shall pay to CHOP within thirty (30) days of receipt of an invoice for such expenses. For clarification, "Financing" means investment of at least $1,000,000."

(c) Amendment of Section 7.6. Effective as of the Amendment Date, Section 7.6 of the Agreement is hereby amended and restated to read in its entirety as follows:

"With regard to expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the Licensed Patent Rights incurred by CHOP prior to June 30, 2020, Licensee will pay CHOP, on the earlier of thirty (30) days post Financing or on September 30, 2020, an amount equivalent to all such patent expenses incurred by CHOP. With regard to expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the Licensed Patent Rights IP incurred by CHOP on or after June 30, 2020, Licensee shall pay to CHOP within thirty (30) days of receipt of an invoice for such expenses. For clarification, "Financing" means investment of at least $1,000,000."

3. Capitalized terms used but not otherwise defined in this Amendment have the meanings provided in the Agreement. This Amendment and the Agreement, as amended and modified by this Amendment, shall constitute and shall be construed as a single instrument. All other terms and conditions of the Agreement not amended herein shall remain in full force and effect.

SIGNATURES ON THE NEXT PAGE

AMENDMENT NO. 1 TO LICENSE AGREEEMENT

SIGNATURE PAGE

IN WITNESS WHEREOF, **CHOP** and **Licensee** have caused this **Amendment** to be duly executed as of the **Amendment Date**.

The Children's Hospital of Philadelphia

DocuSigned by:
Camille Jolly-Tornetta
5/5/2020

Name: Camille Jolly-Tornetta, Ph.D
Date:

Title: Director, Office of Technology Transfer

Orphion Therapeutics

DocuSigned by:
Jason Slakter
5/5/2020

Name: Jason S. Slakter, M.D.
Date:

Title: Chief Executive Officer

EXHIBIT 2

VECTOR PURCHASE AGREEMENT

THIS AGREEMENT is made effective as of the last date written by the undersigned parties in the signature page below, between The Children's Hospital of Philadelphia, a Pennsylvania nonprofit corporation, located at 3401 Civic Center Boulevard, Philadelphia, Pennsylvania 19104 (hereinafter called "**CHOP**"), and Orphion Therapeutics, LLC, a New York limited liability company, having its registered office at 57 Meadow Woods Road, Great Neck, NY 11020 (hereinafter called "**Customer**") (the "**Agreement**").

WHEREAS, CHOP, through its Clinical Vector Core, Center for Cellular and Molecular Therapeutics ("**CCMT**"), has valuable experience, skill, and ability in the production and manufacturing of certain clinical vectors as described in **Schedule 1**, which is attached, incorporated and made part of this Agreement,

WHEREAS, CHOP, through CCMT has manufactured certain Vector Core Material identified in **Schedule 1** (the "**Material**") and Customer wishes to acquire such Material from CHOP,

WHEREAS, the purchase of the Material is necessary for Customer to perform IND-enabling activities as well as clinical trials for certain rare and orphan diseases, as well as for clinical development and commercial activities relating to use of the Material for treatment of such diseases, and

WHEREAS, it is consistent with CHOP's mission in research to develop scientific and medical knowledge to advance the state of patient care, with a particular focus on issues involving the care of children, and the manufacturing and sale of such Material from CHOP to Customer for clinical trial use and clinical application is consistent with CHOP's status as a nonprofit educational healthcare institution.

NOW THEREFORE, the parties, intending to be legally bound, agree as follows:

1. *Scope of Work.*

1.1 *Sale of Material.* On the terms and subject to the conditions set forth in this Agreement, CHOP hereby sells, assigns, transfers, and conveys to Customer, and Customer hereby acquires, accepts and purchases from CHOP, all of CHOP's right, title and interest in the Material. CHOP has delivered and/or shall deliver or cause to be delivered to Customer the Material along with the documents described on **Schedule 1** of this Agreement or as further agreed in writing between CHOP and Customer during the Term of this Agreement (collectively, the "**Related Documents**") to such location as listed in **Schedule 1** hereto or otherwise agreed to by the Parties in writing.

1.2 *Additional QC Testing.* CHOP will perform additional QC testing as listed in **Schedule 2** which is attached hereto and is hereby made part of this Agreement.

1.3 *Manufacturing Standards.* CHOP represents that CCMT manufactured the Material in a manner consistent with applicable legal requirements of the U.S. Food & Drug Administration and cGMP relating to materials to be used in human Phase 1 and Phase 2 clinical trials.

2. [Reserved]

3. *Purchase Price.*

3.1 *Purchase Price Set Forth in Schedule 1.* Customer will pay CHOP the amount specified in **Schedule 1**. This purchase price includes the costs of labor, materials, QC testing, equipment maintenance, fill/finish manufacturing or processes, stability testing, insurance, chemistry, manufacturing

controls ("**CMC**") support, shipping & handling (as applicable). CHOP standard certificate of analysis ("**CoA**") documenting purity, titer and safety for the Material will be provided no later than at the delivery of the Material to Customer. CHOP shall store the Material for up to 6 months after the Effective Date of this agreement at no additional cost, under conditions that do not adversely affect the Material until Customer requests shipment to a single location to be later specified. CHOP may impose storage fees in the event that CHOP stores the Material for longer than six (6) months. Delivery of the entire lot of Material designated for human use may be requested by Customer at any time during the Term of this Agreement. Any other additional costs may be mutually agreed upon in writing between the parties.

4. ***Payment.***

4.1 *Schedule/Payment.* Customer shall make payment to CHOP as per the payment schedule in **Schedule 3** which is attached hereto and made part of this Agreement. In the event that Customer does not accept the CoA within thirty (30) days of CHOP providing the CoA, Customer shall return the Material and Related Documents to CHOP and destroy all copies. CHOP shall provide the Related Documents to Customer promptly upon receipt of this signed Agreement and Customer's payment of the Upfront Payment (as set forth in **Schedule 3**). CHOP shall provide testing samples, in an amount adequate to perform testing and time dependent testing preparation as defined in **Schedule 2**, to Customer promptly upon receipt of a PO for the non-refundable Upfront Payment and receipt of the Upfront Payment. In the event that the number of testing samples requested exceeds 10% of the Material available at CHOP, then CHOP shall adjust the non-refundable Upfront Payment amount set forth in **Schedule 3** and Customer shall pay such greater amount.

4.2 *Testing Milestones.* Customer shall use samples of the Material provided by CHOP to perform certain "Testing Milestones" as described in **Schedule 2** and **Schedule 3** hereto. Upon Customer's satisfaction that the Material meets each Testing Milestone, Customer shall deliver to CHOP a PO for the Material and pay CHOP the balance owed after each Testing Milestone as set forth in Schedule 3. CHOP shall provide and cause to be delivered to Customer the remaining Material after receipt of payment for Testing Milestones 1 and 2 (in the amounts set forth in **Schedule 3**). Customer understands and agrees that after Customer indicates approval of Testing Milestone completion and has received the Material, the Material cannot be returned and the sale of the Material shall be final and Customer shall not be entitled to a refund for any reason.

4.3 *Failure to Pay.* If Customer fails to make any payment due to CHOP under this Agreement, then, without limiting CHOP's remedies hereunder, CHOP may charge interest on the overdue amount at the rate of 2% per annum above the U.S. Federal Reserve Bank's prime rate from time to time. Such interest shall accrue on a daily basis from the due date until actual payment of the overdue amount, whether before or after judgment. Customer shall pay the interest together with the overdue amount. If the Material does not meet the listed specifications, and if Related Documents are not delivered, the parties shall meet to resolve any deficiencies. If resolution cannot be reached within thirty (30) days, the parties will either agree to a price adjustment or Customer may reject the Materials and received an immediate refund. For the avoidance of doubt, the Upfront Payment listed in **Schedule 3** shall be non-refundable.

5. ***Customer Reports to CHOP.***

5.1 *Clinical Trial Reporting.* Customer shall provide CHOP, upon execution of this Agreement, and on June 30 annually thereafter, the name of any clinical trials in which the Material will be used, the number of patients that Customer anticipates will be treated with the Material provided hereunder in the upcoming year, and the number of patients that Customer has treated during the prior year.

5.2 *Severe Adverse Event Reporting.* Customer shall report to CHOP any serious adverse events ("**SAE**") that occur in a clinical trial in which the Material is being used that involve, or potentially involve, the Product Deliverable.

6. Indemnities and Insurance .

6.1 *Customer Assumes Risk.* Customer assumes the risk of any damage, loss, or expense associated with or resulting from any of the following: (A) CHOP's transfer, but not storage at CHOP, of the Material and Related Documents to Customer using the transfer method of Customer's choosing; (B) Customer's conduct of any form of research utilizing the Material and Related Documents; (C) Customer's use, handling, study, storage, return, or disposal of the Material; (D) Customer's actions (or inactions) in any commercial use or further distribution of the Material; (E) Customer's breach of this Agreement; or (F) Customer's failure to conform to law or regulation applicable to this Agreement or the subject matter thereof, to the Material, or to any research or activity conducted by Customer involving the Material and Related Documents.

6.2 *Indemnification.* Customer shall indemnify, defend, and hold harmless CHOP and its officers, trustees, employees, members of its medical and research staff and agents (collectively "**CHOP Indemnitees**") from any claim, loss, judgment, liability, damage, settlement, fine or expense of any kind whatsoever (including reasonable attorneys' fees, interest, penalties and costs) (a "**Claim** arising from: (A) CHOP's use of the transfer method of Customer's choosing to transfer the Material to Customer; (B) Customer's conduct of any research, including, without limitation, any human clinical trials, in any form utilizing the Material or Related Documents; (C) Customer's use, handling, study, storage, return, or disposal of the Material; (D) Customer's actions (or inactions) in any commercial use or further distribution of the Material; (E) Customer's negligence or willful misconduct or any breach by Customer of this Agreement; or (F) Customer's failure to conform to law or regulation applicable to (1) this Agreement or the subject matter hereof, (2) to the Material and Related Documents, (3) to any commercial use or further distribution of the Material and Related Documents, or (4) to any research, including, without limitation, any human clinical trials or other activity conducted by Customer involving the Material or Related Documents provided, however, that to the extent that any such Claim results solely from the gross negligence or willful or intentional misconduct of a CHOP Indemnitee, Customer shall have no such indemnity obligation with respect to any such CHOP Indemnitee.

6.3 *Indemnification Procedure.* To the extent reasonably feasible, CHOP shall notify its indemnitor in writing of any Claim that, in CHOP's reasonable judgment, is likely to lead to a claim for indemnification. Customer shall promptly assume the entire defense of such Claim following CHOP's written notice, and shall, promptly upon such written notice of any prior expenses, reimburse any indemnitee for any expenses, fees or costs incurred by any indemnitee with respect to defense of such Claim prior to the date of Customer's assumption of the defense. The indemnitor shall have the right to manage the defense and settlement of any Claim, except that (A) the indemnitor shall consult with the affected indemnitee regularly with respect to all material matters pertaining to the defense of any such Claim; (B) the indemnitee shall have the right to approve the Indemnitor's choice of counsel to defend any such Claim, which approval shall not be unreasonably withheld by the indemnitee and (C) the indemnitor may not enter into any settlement on behalf of any indemnitee without the indemnitee's prior written approval, which approval shall not be unreasonably withheld, conditioned, or delayed. An indemnitee may not enter into any settlement of any such Claim as to which the indemnitor has an obligation to indemnify such indemnitee without the written permission of the indemnitor, which approval shall not be unreasonably withheld, conditioned, or delayed. An indemnitee shall use commercially reasonable efforts to cooperate with the indemnitor in the defense of the Claim at the indemnitor's sole expense. An indemnitee may hire its own counsel, at its own expense,

to monitor the defense of any Claim in which case the indemnitor shall use commercially reasonable efforts at its sole expense to cooperate with the indemnitee in the defense of the Claim by the indemnitee's selected counsel. Indemnitees and indemnitors may execute such mutually acceptable Confidentiality and Joint Defense Agreements to protect privileged materials as shall be usual and customary in such proceedings and as shall be requested in writing by either.

6.4 *No Warranty; No Refund or Exchange.*
Customer acknowledges that the Material is experimental in nature and may have unknown characteristics or may be otherwise hazardous. Customer agrees that after satisfaction of Testing Milestone 1 and Testing Milestone 2, once the Material is shipped to Customer, the transaction contemplated hereby shall be final and Customer shall not be entitled any return, exchange or refund. THE MATERIAL AND RELATED DOCUMENTS ARE PROVIDED "AS IS" AND CHOP (INCLUDING THE CHOP INDEMNITEES) DISCLAIMS ANY WARRANTY, EXPRESS OR IMPLIED, WITH RESPECT TO THE MATERIAL AND RELATED DOCUMENTS, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE OR ANY WARRANTY THAT THE USE OF THE MATERIAL, RELATED DOCUMENTS, BIOLOGICAL MATERIALS, ANALYTICAL METHODS, TESTING ASSAYS, SOPs, AND OTHER INFORMATION PROVIDED TO CUSTOMER WILL NOT INFRINGE OR VIOLATE ANY PATENT, COPYRIGHT, OR OTHER PROPRIETARY RIGHT OF ANY THIRD PARTY. Without limitation of the foregoing, CHOP (including the CHOP Indemnitees) makes no representation or warranty as to the identity, purity, safety, fitness, or activity of the Material except for the attributes as indicated on the CoA. CUSTOMER'S EXCLUSIVE REMEDY UNDER THIS AGREEMENT IS, AT CHOP 'S SOLE OPTION, A REFUND FOR THE MATERIAL ACCORDING TO CUSTOMER'S SPECIFICATIONS TO BE PROVIDED AT SUCH TIME (IF APPLICABLE). IN NO EVENT WILL ANY PARTY TO THIS AGREEMENT BE LIABLE FOR ANY CONSEQUENTIAL, INCIDENTAL, SPECIAL, OR INDIRECT DAMAGES, INCLUDING WITHOUT LIMITATION, DAMAGES FOR LOSS OF PROFITS, BUSINESS INTERRUPTION, LOSS OF BUSINESS INFORMATION, OR PROPERTY DAMAGE SUSTAINED FROM THE USE OF, OR INABILITY TO USE, ANY MATERIAL, EVEN IF THAT PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. AS TO ANY LIABILITY NOT SUBJECT TO THE FOREGOING AND EXCLUDING THE INDEMNIFICATION OBLIGATIONS SET FORTH IN SECTION 6.2, A PARTY'SMAXIMUM LIABILITY WILL NOT EXCEED THE AGGREGATE AMOUNT PAID BY CUSTOMER TO CHOP FOR THE MATERIAL IN QUESTION. WITHOUT LIMITATION OF THE FOREGOING, NEITHER PARTY (INCLUDING ANY INDEMNITEES) MAKES ANY REPRESENTATION OR WARRANTY AS TO THE SAFETY, FITNESS, OR ACTIVITY OF THE MATERIAL.

6.5 *Insurance.* In the event that Customer uses the Material for human clinical studies, Customer shall obtain and maintain for a period of five (5) years after the execution of this Agreement insurance policies of such types, including comprehensive general liability, products liability and completed operations liability Insurance, all risk property insurance, including transit coverage in an amount equal to the full replacement value of its property while in a CHOP facility, and in such amounts as shall be reasonably required to protect itself from potential liabilities, risks and claims arising under this Agreement and/or from the performance of Customer's acts or omissions arising in connection with or under this Agreement but in no case less than $3 million annual limits per policy or $5 million annual aggregate. Customer shall obtain a waiver of subrogation clause from its property insurance carrier in favor of CHOP. In the event that Customer plans to use the Material in a clinical trial, Customer shall also obtain and maintain Clinical Trials Liability Insurance with a per occurrence limit of not less $10 million and warrants and represents that such Clinical Trial Liability insurance will be in force at the time that Customer commences any clinical trial. Clinical Trials Liability insurance shall be primary and noncontributory with insurance, deductibles, or self-insurance maintained by CHOP. CHOP shall be a named additional insured on Customer's Clinical Trials Liability

Insurance. Customer shall also obtain and maintain worker's compensation insurance as required by state law. Customer shall add CHOP as an additional insured to Customer's comprehensive general liability policy, and Customer shall provide CHOP with certificates from each of Customer's insurers issuing insurance required under this Agreement. All policies of insurance required hereunder shall be placed with recognized prestige insurers. All insurance required pursuant to this Agreement shall be on an occurrence basis unless a particular type of insurance is not available on an occurrence basis on commercially reasonable terms and is available on commercially reasonable terms only on a claims made basis, in which case such insurance shall include (or subsequently be made to include) "tail" coverage in the event of this Agreement's expiration or termination (provided that tail coverage is available on commercially reasonable terms).

7. ***Use of CHOP Name.***

Customer will not use, directly or by implication, the name, logo, abbreviation, or any identifying mark of CHOP, or the name of any member of the staff thereof, in any publicity, advertising or in any other manner without the prior written consent of CHOP, except as specified in Section 10.

8. ***Invention and Patent Rights; Licenses.***

8.1 *Ownership.* It is recognized and understood that all inventions and technologies owned by CHOP or Customer and existing on the effective date of this Agreement shall remain the separate property of CHOP or Customer, respectively. Such inventions and technologies are not affected by this Agreement, and none of the parties shall have any claims or rights under or as a result of this Agreement to or in such separate inventions or technologies of the other parties. The parties have entered into a Confidential Disclosure Agreement dated as of August 19, 2018 (the "**CDA**") and the Material and Related Documents constitute Confidential Information under the CDA subject to the terms and conditions thereof, provided, that Customer's use of the Material and Related Documents as contemplated in this Agreement, including in confidential submissions to government regulatory authorities for the purpose of obtaining required approvals, is permitted subject to Customer obtaining any necessary consents from Spark or others as contemplated in Section 8.2 below. In addition, the Parties agree that any information, documents or materials accessed by Customer during any GMP audit shall be subject to the confidentiality obligations set forth in the CDA and CHOP may require a separate confidentiality agreement to govern any Customer audit prior to the occurrence of such audit.

8.2 *Spark License.* Customer understands and acknowledges that Spark Therapeutics, Inc. ("**Spark**") holds an exclusive license from CHOP for certain patents, know-how, and data, including the ability to reference the DMF on file with the FDA for Commercial Purposes. Customer understands that CHOP has reserved limited rights to manufacture the Material and as such, among other limitations, only retains the authority to manufacture the Material for purposes that do not exceed *in vitro* studies, lab animal studies, Phase 1, Phase 1/2, and/or Phase 2 clinical trials. Customer also understands that CHOP does not possess the right to manufacture the Material for commercial use. Customer hereby represents to CHOP that (a) Customer is not relying on CHOP for rights to use the Material or Related Documents for any purpose that exceeds CHOP's rights as described above and (b) Customer has obtained from Spark, and others if applicable, all necessary license, sublicense, and other rights necessary for Customer and its employees, agents, and contractors to use or sell the Material and Related Documents for clinical, therapeutic and/or commercial purposes as contemplated in connection with this Agreement. Customer agrees to procure and provide any documentation reasonably requested by CHOP confirming Customer's rights, from Spark or others, to use the Material and Related Documents as contemplated hereunder. Spark has confirmed to CHOP that this agreement is in place, however, there exists a clause in the Orphion/Spark agreement that prohibits disclosure of the agreement itself.

9. ***Export Control.***

Customer shall not disclose or provide to CHOP or any CHOP trustee, officer, employee or agent of CHOP or other person in a position to receive such information from Customer (each a "**Customer PERSON**") any information subject to the licensing provisions of International Traffic In Arms Regulations (ITAR) under 22 CFR §§ 120-130, and Export Administration Regulations ("**EAR**") under 15 CFR §§ 730- 774, without limitation, without the prior written notice to and advance approval by CHOP, such approval not to be unreasonably withheld, conditioned, or delayed. As a condition of such disclosure as approved by CHOP, Customer shall require each Customer representative receiving such information to agree to restrictions on further disclosure similar to those contained in this Section.

10. ***Publication.***

Customer and CHOP agree that in the event the product manufactured by CHOP results in a scientific publication, Dr. Van Der Loo or a representative from CHOP assigned by Dr. Van Der Loo will be co-author as deemed appropriate in accordance with standard, peer reviewed, academic practices for publications.

11. ***Hazardous and Regulated Material.***

Customer and CHOP shall package, label, transport, and ship hazardous materials, or material containing hazardous materials, and any other regulated materials, in accordance with all applicable federal, state, and local laws, rules, ordinances, and regulations, and shall furnish any appropriate documentation or Material Data Safety Sheets. Prior to each shipment of any hazardous regulated materials, the shipping party shall notify the carrier, handler, and receiver of such shipment of the nature of such shipment by such means of communication as will allow for the proper preparation for acceptance of the delivery and shall identify same on all shipping documents. The shipping party shall be solely responsible for notifying carriers and other handlers of any risks inherent in any such shipments.

12. ***Fair Market Value; No Inducements.***

Each party represents that the compensation provided under this Agreement represents the fair market value of the Material, has been negotiated in an arm's-length transaction, and has not been determined in any manner with regard to any implicit or explicit agreement to provide favorable procurement decisions with regard to the value or volume of any business or referrals generated between the Parties.

13. ***Notices.***

Any notices required to be given or which shall be given under this Agreement shall be in writing and delivered by first-class mail or facsimile transmission addressed to the parties as follows:

For Customer:

Orphion Therapeutics, LLC
57 Meadow Woods Road
Great Neck, NY 11020
Attention: Jason S. Slakter, MD, CEO

For CHOP:

The Children's Hospital of Philadelphia
Colket Translational Research Building
3501 Civic Center Blvd., Suite 2200
Philadelphia, PA 19104
Attention: Vice President, Technology Transfer, Commercialization and Innovation

With a copy to:

The Children's Hospital of Philadelphia
Office of General Counsel
Roberts Center for Pediatric Research
2716 South Street – 20th Floor
Philadelphia, PA 19146
legal@chop.edu

14. *General Provisions.*

14.1 *Laws and Regulations*. This Agreement is subject to all local, state and federal laws and regulations. In carrying out the purpose of this Agreement, each of CHOP and Customer agrees that its activities will be conducted in compliance with all relevant laws and regulations in force at the United States federal, state and local levels. Customer shall also conform to the requirements and standards of the Association for Assessment and Accreditation of Laboratory Animal Care International in all activities undertaken by Customer related to this Agreement. This Agreement is governed by the laws of the Commonwealth of Pennsylvania. Any legal action involving this Agreement, or the Material will be adjudicated in the courts residing in Philadelphia, Pennsylvania, without regard to its conflict of laws doctrine.

14.2 *Assignment*. Customer may transfer or assign its rights and obligations under this Agreement, without consent if such assignment is a Qualified Assignment to an Affiliate or a successor to all or substantially all of its business or assets relating to this Agreement, whether by sale, merger, operation of law or otherwise, provided that, in the event of such sale or merger, such assignment is a "Qualified Assignment" and that Customer notifies CHOP within ten (10) days of any Qualified Assignment, and Customer provides CHOP a copy of such assignment (subject to redaction of any financial or confidential parts of the assignment document or other parts of the assignment document that relate to assets or parts of the business that are not relevant to this Agreement).

For the purposes of this Agreement, a "Qualified Assignment" means any assignment that:

(a) is made in compliance with applicable laws;

(b) includes the assignee's written acknowledgement of and written agreement to all of Customer's obligations under the Agreement;
(c) is made to an assignee that is, and will be after giving effect to the relevant assignment, Solvent;
(d) is made to an assignee that is not subject at the time of such assignment to any order, decree or petition providing for (i) the winding-up or liquidation of such person, (ii) the appointment of a receiver over the whole or part of the assets of such person or (iii) the bankruptcy or administration of such person;
(e) is not a voidable fraudulent conveyance;
(f) is made to an assignee that is at the time of such assignment not debarred under 21 U.S.C. §30 or under investigation or threatened to be debarred under 21 U.S.C. §30; and
(g) will not cause a material increase in taxes, costs or expenses to CHOP other than as a result of increased income to CHOP (unless the assignee has agreed to compensate CHOP for the same).

For purposes of this Paragraph 14.2, "Solvent" means, with respect to any person as on any date of determination, that as of such date, (i) the value of the assets of such person is greater than the total amount of liabilities (including contingent and unliquidated liabilities) of such person, (ii) such person is able to pay all liabilities of such person as such liabilities mature and (iii) such person does not have unreasonably small capital (taking into account such person's

obligations hereunder). In computing the amount of contingent or unliquidated liabilities at any time, such liabilities shall be computed at the amount that, in light of all the facts and circumstances existing at such time, represent the amount that can reasonably be expected to become an actual or matured liability.

Except as provided herein, the Customer and CHOP agree that their rights and obligations under this Agreement may not be transferred or assigned without the prior written consent of the other party hereto, which consent may be withheld in such other party's sole discretion.

Notwithstanding anything to the contrary in this Paragraph 14.2 or elsewhere in this Agreement, CHOP may sell, transfer or assign its rights to any third party to receive payments under this Agreement, and CHOP may disclose Confidential Information of Customer to one or more third parties (provided such third part is under obligations of confidentiality to CHOP at least as stringent as those in this Agreement) in connection with any such assignment to enable the third party(ies) to evaluate and monitor any such purchase.

Any attempted assignment, delegation or transfer in violation of this Paragraph 14.2 will be void. Any permitted assignee will assume all assigned obligations of its assignor under this Agreement. The terms and conditions of this Agreement will inure to the benefit of, and be binding upon, the legal representatives, successors and permitted assigns of the parties to this Agreement.

14.3 *Severability.* If any provision of this Agreement becomes or is declared illegal, invalid, or unenforceable, the provision will be divisible from this Agreement and deemed to be deleted from this Agreement. If the deletion substantially alters the basis of this Agreement, the parties will negotiate in good faith to amend the provisions of this Agreement to give effect to the original intent of the parties.

14.4 *Independent Contractors.* CHOP and Customer are independent contractors and neither is an agent, joint venturer, or partner of the other. No employee of CHOP may be listed by Customer as an investigator or co-investigator under this Agreement without the express written approval of CHOP.

14.5 *Prevailing Terms.* In the event of any inconsistency between the terms of this Agreement and the documents referenced or incorporated into this Agreement, the terms of this Agreement prevail.

14.6 *Entire Agreement.* This Agreement, the Scope of Work and other pertinent documentation attached hereto represents the entire agreement and understanding between the parties with respect to its subject matter. It supersedes all prior or contemporaneous discussions, representations, or agreements, whether written or oral, of the parties regarding this subject matter.

14.7 *Waiver.* The waiver by either party of a breach of any provision of this Agreement shall not operate as or be considered a waiver by that party of any subsequent breaches.

14.8 *Amendments or Changes.* Amendments or changes to this Agreement must be in writing and signed by the parties' authorized representatives.

14.9 *Force Majeure.* Neither CHOP nor Customer will be liable for delay or non-performance of any of its obligations hereunder or its performance of the services to the extent that such performance is prevented, prohibited or delayed by any circumstance for reasons beyond its control including without limitation, labor disputes, fire, flood, natural disaster, war blockade, military operations, riot, civil commotion, plant breakdown, power outage, pandemic, epidemic, health emergency, computer or other equipment failure or non-delivery or delays in delivery by any other suppliers of goods or services utilized in the

performance of services under this Agreement, provided that such non-performing party completes the services within a reasonable time after such circumstances are resolved.

14.10 *Conflicts and Ethical Standards of Conduct.* Customer and CHOP agree that, to the best knowledge of each, there exist no conflicts of interests between Customer and CHOP or its employees. Customer hereby represents that it has neither received nor given gifts or gratuities to any member of the CHOP community, nor participated in any other unethical conduct in connection with this Agreement. If, at any time, CHOP determines that Customer is in violation of any representation under this Section, CHOP may cancel this Agreement upon written notice to Customer, and CHOP shall have no further obligation to Customer.

14.11 *Equal Opportunity Employer.* CHOP is an Equal Opportunity Employer. If applicable, CHOP and Customer shall abide by the requirements of 41 CFR 60-300.5(a). This regulation prohibits discrimination against qualified protected veterans, and requires affirmative action by covered prime contractors and subcontractors to employ and advance in employment qualified protected veterans. If applicable, CHOP and Customer shall abide by the requirements of 41 CFR 60-741.5(a). This regulation prohibits discrimination against qualified individuals on the basis of disability, and requires affirmative action by covered prime contractors and subcontractors to employ and advance in employment qualified individuals with disabilities. Customer warrants that it will not discriminate in the performance of this Agreement or employment against any person because of age, race, color, religion, national or ethnic origin, sex, sexual orientation, gender identity, marital status, veteran status, or disability. This Section 14.11 will not prevent Customer from designing and administering clinical trials that may include or exclude persons of a particular age, race, color, religion, national or ethnic origin, sex, sexual orientation, gender identity, marital status, veteran status, or disability as necessary for the design of the clinical trial. Customer also warrants that it will comply with all applicable executive orders, and federal, state, and local laws, regulations, and rules, relating to nondiscrimination, equal employment opportunity, and affirmative action.

14.12 *Third Parties.* Nothing contained in this Agreement shall be construed to create any rights or benefits in a third party.

14.13 *Survival.* The rights and obligations of each of CHOP and Customer, which by intent or meaning have validity beyond such termination or expiration, shall survive the termination or expiration of this Agreement, including but not limited to Sections 5, 6, 8, 9, 10, 11, 13 and 14.

[*Signature Page Follows*]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed as of the last day written by the undersigned parties below.

THE CHILDREN'S HOSPITAL OF PHILADELPHIA

By _____
Name: Zev Sunleaf
Title: Vice President-TTIRC
Date: September 11, 2020

ORPHION THERAPEUTICS, LLC

By _____
DocuSigned by:
Jason Slakter
03E939FF5D7641B...
Name: Jason Slakter, MD
Title: Chief Executive Officer
Date 9/11/2020

By its signature below, Spark Therapeutics, Inc. hereby acknowledges and consents to CHOP's delivery to Customer of the Material, and other items listed on **Schedule 1** as contemplated in this Agreement.

SPARK THERAPEUTICS, INC.

By _____
Name:
Title:
Date:

Execution Version

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed as of the last day written by the undersigned parties below.

THE CHILDREN'S HOSPITAL OF PHILADELPHIA	ORPHION THERAPEUTICS, LLC
By _____	By _____
Name:	Name:
Title:	Title:
Date:	Date

By its signature below, Spark Therapeutics, Inc. hereby acknowledges and consents to CHOP's delivery to Customer of the Material, and other items listed on **Schedule 1** as contemplated in this Agreement.

SPARK THERAPEUTICS, INC.

By _____
Name: PAUL J. SAVIDGE
Title: GENERAL COUNSEL
Date: SEPT. 11, 2020

Schedule 1

Description of Material and Related Documents

1. *Material* (all of which is Confidential Information under this Agreement)
    a. Description of the starting materials, including a description of:
        i. HEK293 master/working cell bank
        ii. Plasmids for tri-transfection
    b. Description of the raw materials
        i. Raw materials used in working cell bank production (composition and final concentration)
        ii. List of reagents, solvents, and auxiliary materials for used in the manufacture of AAV2-CAG-TPP1
        iii. List of buffers used in the manufacture of AAV2-CAG-TPP1
    c. Description of AAV2-CAG-TPP1 lot A1804C-C
        i. Letter of Authorization for FDA to review the Lot release file and access to the Lot release file for review during the GMP audit.
        ii. Number of vials available for sponsor use, volume of aliquoting and storage temperature
2. *Related Documents* (all of which is Confidential Information under the CDA)
    a. With regards to the drug substance:
        i. Description of manufacturing process and process controls for the drug substance, including a description of batch scale, all raw and starting materials used in manufacturing, and any materials of human or animal origin.
        ii. List of the names and addresses of all firms involved in production and testing.
        iii. Summary of characterization information and known or expected product/process impurities and contaminants.
        iv. Summary of control specification and batch analysis data for all IND-enabling drug substance batches. Access to these documents will be provided to the Customer during the GMP audit subject to confidentiality restrictions required by CHOP.
        v. Description of reference standards and container closure system relevant to the drug substance.
    b. With regards to the drug product:
        i. Summary of components and concentrations of drug product, as well as CCS details and documentation of batch scale.
        ii. Summary of manufacturing process and process controls, including flow diagrams, batch formulas, and filter qualifications.

iii. List of the names and addresses of all firms involved in production and testing.

iv. Summary of control specification and batch analysis data for all IND-enabling drug product batches, including information on test methods and verification/validation status. Access to these documents will be provided to the Customer during the GMP audit.

v. Summary of reference standards, if different than those of drug substance.

vi. Description of container closure system, including the name and address of the manufacturer, part numbers, drawings, and acceptance criteria.

c. With regard to the cell bank system and plasmids

i. History cell line document

ii. cGMP release of the Master and the working cell banks (specifications)

3. Any documents required for GMP Audit by Customer

i. Access to all documents required for GMP audit will be provided to the Customer during the audit period.

4. Additional QC testing

i. QC testing listed in Schedule 2, costing included in Exhibit A and Schedule 3.

Purchase Price of Material

$ 674,652 (GMP Product see Exhibit A: Cost Estimate 010920-02)

$7,537 (Additional QC testing see Exhibit A: Cost Estimate 072420-01)

TOTAL: $682,189

Execution Version

"Exhibit A"
"Statement of Work"

The Children's Hospital of Philadelphia®
RESEARCH INSTITUTE

CENTER FOR CELLULAR & MOLECULAR THERAPEUTICS

DATE: 1/9/20
ESTIMATE : 010820-02

SERVICE PROVIDER	CUSTOMER
Clinical Vector Core Center for Cellular & Molecular Therapeutics The Children's Hospital of Philadelphia 3501 Civic Center Boulevard Philadelphia, PA 19104 Phone: (267) 425-2011 E-mail: vanderlooj@email.chop.edu	Jason Slakter, MD Orphion Therapeutics, LLC 111 Great Neck Road, Suite 300 Great Neck, NY 11021 Phone: (917) 951-5659 E-mail: Jason.Slakter@orphiontherapeutics.com

DESCRIPTION
Viral vector SPK-1002 (AAV-TPP1; Lot A2FP1-A1804C-C) was manufactured in compliance with current Good Manufacturing Practices (cGMP) for early phase clinical trials. Product was manufactured in two (2) batches that were combined into a single lot with a titer of 2.12E12 vg/mL at 0.25 mL/vial (416 vials filled). Release testing was conducted as required by the FDA for early phase clinical trials. Material was originally manufactured for CHOP. Clinical excipient and stability testing services are available upon request for additional cost.

Number of Batches	2	Grade: GMP for Early Phase Clinical Trials

Variable Cost	Batches	Weeks	Cost Each	Total Cost
Labor		8	$ 26,355	$ 210,841
Facility/Equipment		8	$ 3,142	$ 25,136
Materials	2		$ 27,617	$ 55,234
Quality Control	2		$ 1,481	$ 2,962
Fixed Cost	**Lot**	**Weeks**	**Cost Each**	**Total Cost**
Labor		12	$ 7,473	$ 89,672
Materials	1		$ 36,172	$ 36,172
Fill & Finish	1		$ 1,421	$ 1,421
Release Testing	1		$ 81,783	$ 81,783
Shipping & Handling	1		$ 3,150	$ 3,150
Other	**Each**	**Weeks**	**Cost Each**	**Total Cost**
Regulatory	1		$ 500	$ 500
Insurance	1		$ 12,092	$ 12,092
Excipient clinical (1 mL/vial)	0		$ 100	$ -

Direct Cost	$ 518,983
Hospital Surcharge (Industry Rate)	$ 155,689
Total	$ 674,852

Estimate valid until NA

Execution Version

The Children's Hospital of Philadelphia®
RESEARCH INSTITUTE

CENTER FOR CELLULAR & MOLECULAR THERAPEUTICS

DATE 7/24/20
ORIGINAL ESTIMATE : 072420-01

DESCRIPTION	
Client Name	Orphios Therapeutics
Product Name	AAV2-TPP1
Product Lot Number	A1804C-C
DOM	21DEC2018
CoA Date	15APR2019
Stability Time Point (Months)	As defined by sponsor

Test description	Each	Number	Total
Vector Genome Titer by Real Time Q-PCR	$ 875	1	$ 875
Protein Impurities by SDS-PAGE/ Silver Stain	$ 1,031	1	$ 1,031
Appearance by Visual Inspection	$ 62	1	$ 62
Isolator Sterility USP, EP, JP	$ 4,944	1	$ 4,944
pH by Potentiometry	$ 148	1	$ 148
Shipping & Handling	$ 844	1	$ 844

Direct Cost	$ 5,798
Hospital Surcharge (Industry Rate)	$ 1,739
Total	$ 7,537

Schedule 2

Testing requirements for Lot acceptance

This schedule details the validation testing needed to validate the material for the IND enabling tox program as well as use as a GMP product in the clinical trial.

	GLP TOX study (Testing Milestone 1)		Clinical Study (Testing Milestone 2)	
	CHOP	CRO	CHOP	CRO
Assays				
Vector genome titer by qPCR (vg/mL)	X		X	
Infectious titer (IU/mL)		X		X
Infectious titer ratio		X		X
Purity by SDS-PAGE	X		X	
Potency assay/ expression assay		X		X
Aggregation by DLS		X		X
Subvisible particles				X
Appearance	X		X	
Sterility	X		X	
pH	X		X	
Container closure integrity				X

Schedule 3

Payment Schedule

Total $682,189

Type	Testing Milestones	Amount
Upon execution of Agreement ("**Upfront payment**")	N/A	**The greater amount of either the number of viles tested or 10% of Purchase Price ($68,219)**
Testing Milestone 1	Confirmation of suitability of Material for IND enabling tox program as defined in Schedule 2, and available quantities of Material for such studies	**30% of Purchase Price ($204,657)**
Testing Milestone 2	Confirmation of suitability of Material for clinical trial per GMP as defined in Schedule 2, identification of relabeling procedure by Orphion or outside entity selected by Orphion, successful GMP audit of Vector Core facility, and available quantities of Material for clinical trial after completion of testing	**60% of Purchase Price ($409,313)**

The Upfront payment is non-refundable.

EXHIBIT 3

Zev Sunleaf

Vice President
Technology Transfer, Commercialization & Research Contracts
15140 Roberts Pediatrics Research Center
2716 South Street
Philadelphia, PA 19146
T 267-425-3029

June 9, 2023

VIA First Class Mail

Dr. Jason Slakter
Orphion Therapeutics
57 Meadow Woods Road
Great Neck, NY 11020

Re: Notice of Breach of License Agreement by and among The Children's Hospital of Philadelphia ("CHOP") and Orphion Therapeutics ("Licensee") dated October 28, 2019 as amended on May 5, 2020 (the "Agreement").

Dear Dr. Slakter,

This letter constitutes formal notice of breach of the Agreement. Please be advised that the Licensee is in material breach of the following terms of the Agreement:

- 7.5 Patent Expenses. With regard to expenses associated with the preparation, filing, prosecution, and maintenance of CHOP Co-Owned IP incurred by CHOP on or after June 30, 2020, Licensee shall pay to CHOP within thirty (30) days of receipt of an invoice for such expenses.
- 7.6 Patent Expenses. With regard to expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the Licensed Patent Rights IP incurred by CHOP on or after June 30, 2020, Licensee shall pay to CHOP within thirty (30) days of receipt of an invoice for such expenses.
- 10.1 Licensee's Efforts. Licensee shall use its reasonable best efforts to bring the Licensed Products or Licensed Processes to Practical Application and performance of the Milestones at Appendix C.
- Appendix C Milestone-the filing of IND for TPP1 Retinal Program by March 2021
- Appendix C Milestone-the filing of IND for MPSIIIa Program by March 2022

Per Section 13.2 of the Agreement, CHOP intends to terminate the Agreement upon the expiration of the notice period on September 7, 2023 (the "Termination Date"). Licensee must continue to pay to CHOP all amounts, including accrued interest, owed to CHOP under the Agreement through the Termination Date.

Sincerely,

Children's Hospital of Philadelphia
RESEARCH INSTITUTE

EXHIBIT 4

PAUL HASTINGS

1(650) 320-1813
edwardhan@paulhastings.com

June 14, 2023

VIA EMAIL AND US MAIL

Zev Sunleaf, Vice President Technology Transfer, Commercialization & Research Contracts
The Children's Hospital of Philadelphia
Roberts Pediatric Research Center
2716 South Street
Philadelphia, PA 19146

Re: Breaches of Vector Purchase Agreement and Patent License Agreement

Dear Mr. Sunleaf:

Reference is made to (1) The Children's Hospital of Philadelphia Patent License Agreement -- Exclusive between Orphion Therapeutics, Inc. ("Orphion") and The Children's Hospital of Philadelphia ("CHOP"), dated as October 28, 2019 ("License Agreement"), and (2) the Vector Purchase Agreement between Orphion and CHOP, dated September 11, 2020 ("Purchase Agreement"). Capitalized terms set forth but not otherwise defined herein shall have the meanings set forth in those agreements. Paul Hastings LLP represents Orphion in this matter so please direct any future correspondence to my attention. Please note that, pursuant to the notice provisions of the Purchase Agreement, we are also sending a copy of this letter to CHOP's Office of General Counsel.

Pursuant to the Purchase Agreement, Orphion purchased certain GMP Material necessary for Orphion to perform IND-related activities as well as clinical trials. As you know, this Material is critical to Orphion's development and research activities related to the treatment of rare and serious genetic disorders, as well as Orphion's ongoing survival as a viable therapeutics company. Under Section 3.1 of the Purchase Agreement, that Material was to be stored by CHOP and delivered to Orphion later "as may be requested . . . at any time during the Term of this [Purchase] Agreement." There is no provision in the Purchase Agreement that allows CHOP to unilaterally destroy or sell the Material to another party.

However, during communications about a possible investment in Orphion by CHOP, on June 1, 2023, you revealed in an email that "we only have 125 vials of clinical TPP1 aliquoted to 0.25mL @ 2.12E12 vg/ml available [and] no longer have the 400 vials from 3 years ago" that Orphion acquired under the Purchase Agreement. As an initial matter, that revelation was shocking to Orphion and contrary to the consistent communication between the parties about the status of Orphion's activities and plans. As CHOP knows, that Material is absolutely essential to Orphion and cannot be timely replaced or substituted. Moreover, CHOP's attempt to use the passage of time as some excuse for its actions here are unfounded. First, and as noted above, there is nothing in the Purchase Agreement that allows CHOP to disregard its obligations because some amount of time has passed. Second, that time pretext ignores that, in a January 3, 2022 email to Jason Slakter of Orphion with a cc to Stacey Piecyk and Olga Zelenaia of CHOP, Johannes C. Van Der Loo stated "[c]onfirming that [CHOP] will maintain the material in GMP storage." In other words, just last year, CHOP confirmed it would store the Material and make it available as Orphion needed. Unfortunately, despite that 2022 assurance from CHOP and the clear terms of the Purchase Agreement, at some point CHOP apparently either destroyed or sold the Material to another purchaser. CHOP thereafter ignored Orphion's repeated requests for information and clarity about what happened to the 400 vials of GMP Material.

PAUL
HASTINGS

Instead of providing information related to the 400 vials of Material and what CHOP could do to mitigate or resolve its malfeasance on this matter, you sent a letter dated June 9, 2023 on behalf of CHOP ("June 9 Letter") purporting to provide "formal notice of breach of the [License] Agreement." That June 9 Letter is nothing more than a transparent attempt to deflect CHOP's wrongdoing with respect to the missing 400 vials of Material. In fact, in the same June 1st email where you informed Orphion that 400 vials of Material were missing, you stated "we also need to amend the license to terminate rights to the MPS III IP and program. Orphion has missed the original agreement milestones in Appendix C of the License Agreement, and have missed the previously agreed to extensions in the September 2021 update report as well. Looking at your current timelines and investments, we don't see a plan to move this program forward in a manner consistent with the agreement. Instead of terminating the entire agreement, we are willing to amend to pull this program out." It was not until repeated outreach by Orphion inquiring about the 400 vials of Material and Dr. Slakter providing email correspondence confirming that CHOP would maintain the Material that CHOP wrongfully and in bad faith decided to claim breach of and its intent to terminate the License Agreement. What makes the June 9 Letter particularly disingenuous is that CHOP's apparent destruction or sale of the 400 vials of Material directly impacts Orphion's ability to cure one of the supposed breaches.

CHOP's actions as described above are troubling for myriad reasons and cause Orphion to question whether CHOP or its delegates ever intended to comply with CHOP's obligations under either agreement. Instead, Orphion believes CHOP may have engaged in fraudulent activity as well as breached the terms and spirit of both the Purchase Agreement and License Agreement. Accordingly, Orphion demands that CHOP provide all information related to the 400 vials of Material including but not limited to: (1) what happened to those vials; (2) when; (3) who was responsible for the action and who approved; (4) who else was involved in that action and/or knew about the action; (5) why CHOP did not notify Orphion until June 1, 2023 of the missing 400 vials; (6) are the 125 vials identified in your June 1st email GMP or non-GMP grade material; and (7) are there any other vials of the Material (other than the 125 vials)? Orphion expects this information in writing by June 21, 2023.

Orphion specifically reserves all of its rights and remedies with respect to the contents of this letter and the Purchase Agreement and License Agreement, including but not limited to any claims that Orphion may assert against CHOP and its representatives for fraud, negligent misrepresentation, breach of contract, and/or unfair business practices.

Sincerely,

Edward Han
of PAUL HASTINGS LLP

cc: Office of General Counsel [VIA EMAIL (legal@chop.edu) AND US MAIL]
The Children's Hospital of Philadelphia
Roberts Center for Pediatric Research
2716 South Street, 20th Floor
Philadelphia, PA 19146

Jeff Hartlin, Esq., Paul Hastings LLP

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF

----------x

ORPHION THERAPEUTICS, INC.,

Plaintiff/Petitioner,

- against -

Index No. 655222/2024

THE CHILDREN'S HOSPITAL OF PHILADELPHIA; LATUS BIO, INC.; and BEVERLY DAVIDSON,

Defendant/Respondent.

----------x

NOTICE OF ELECTRONIC FILING
(Consensual Case)
(Uniform Rule § 202.5-b)

You have received this Notice because:

1) The Plaintiff/Petitioner, whose name is listed above, has filed this case using the New York State Courts E-filing system ("NYSCEF"), and

2) You are a Defendant/Respondent (a party) in this case.

- **If you are represented by an attorney:**
  Give this Notice to your attorney. (Attorneys: see "Information for Attorneys" pg. 2).

- **If you are not represented by an attorney:**
  You will be served with all documents in paper and you must serve and file your documents in paper, unless you choose to participate in e-filing.

  If you choose to participate in e-filing, you must have access to a computer and a scanner or other device to convert documents into electronic format, a connection to the internet, and an e-mail address to receive service of documents.

  The **benefits of participating in e-filing** include:

  - serving and filing your documents electronically
  - free access to view and print your e-filed documents
  - limiting your number of trips to the courthouse
  - paying any court fees on-line (credit card needed)

To register for e-filing or for more information about how e-filing works:

- visit: http://www.nycourts.gov/efile-unrepresented or
- contact the Clerk's Office or Help Center at the court where the case was filed. Court contact information can be found at www.nycourts.gov

To find legal information to help you represent yourself visit www.nycourthelp.gov

Information for Attorneys

An attorney representing a party who is served with this notice must either consent or decline consent to electronic filing and service through NYSCEF for this case.

Attorneys registered with NYSCEF may record their consent electronically in the manner provided at the NYSCEF site. Attorneys not registered with NYSCEF but intending to participate in e-filing must first create a NYSCEF account and obtain a user ID and password prior to recording their consent by going to www.nycourts.gov/efile

Attorneys declining to consent must file with the court and serve on all parties of record a declination of consent.

For additional information about electronic filing and to create a NYSCEF account, visit the NYSCEF website at www.nycourts.gov/efile or contact the NYSCEF Resource Center (phone: 646-386-3033; e-mail: nyscef@nycourts.gov).

Dated: October 4, 2024

Kathleen E. Reilly
Name
Sadis & Goldberg LLP
Firm Name

551 Fifth Avenue, 21st Fl.
Address
New York, NY 10176

(212) 573-8426
Phone

kreilly@sadis.com
E-Mail

To: See Service List on Next Page

6/6/18

The Children's Hospital of Philadelphia
3401 Civic Center Blvd.
Philadelphia, PA 19104

Latus Bio, Inc.
c/o The Corporation Trust Company
Corporation Trust Center
1209 Orange St.
Wilmington, DE 19801

Beverly Davidson
The Children's Hospital of Philadelphia
Clinical Vector Core Facility
3501 Civic Center Blvd.
Philadelphia, PA 19104

EXHIBIT B

SPONSORED RESEARCH AGREEMENT

This Sponsored Research Agreement ("Agreement") is made as of October 13, 2020 ("Effective Date") by and between The Children's Hospital of Philadelphia, a Pennsylvania nonprofit corporation ("CHOP"), with offices located at 3401 Civic Center Boulevard, Philadelphia, Pennsylvania 19104, and Orphion Therapeutics, LLC, a corporation ("Sponsor"), having a place of business at 57 Meadow Woods Road, Great Neck, NY 11020 (each a "Party," and collectively the "Parties").

WHEREAS, CHOP and Sponsor have entered into a Patent License Agreement – Exclusive, effective as of October 28, 2019 (the "License Agreement"); and

WHEREAS, Sponsor desires to fund the Research Project, as defined below; and

WHEREAS, Sponsor desires to support such Research Project conducted by CHOP in accordance with the terms and conditions of this Agreement; and

WHEREAS, the Research Project contemplated by this Agreement is of mutual interest to Sponsor and CHOP, and furthers the educational, scholarship, patient care, and research objectives of CHOP as a nonprofit, tax-exempt educational institution, and may benefit Sponsor, CHOP, and the public through the creation or discovery of new scientific knowledge;

NOW, THEREFORE, in consideration of the premises and of the mutual covenants contained herein, and intending to be legally bound hereby, the Parties hereto agree as follows:

ARTICLE 1: DEFINITIONS

1.1 "Background Intellectual Property" means certain inventions, know-how, technologies, and intellectual property of each Party that are existing as of the Effective Date or that are developed or acquired by a Party subsequent to the Effective Date but outside the performance of the Research Project.

1.2 "CHOP Intellectual Property" means any and all inventions, discoveries, materials, works of authorship (including computer software) and copyrighted materials that are created, conceived, discovered or reduced to practice solely by employees of CHOP during the performance of the Research Project.

1.3 "Confidential Information" means any information that is disclosed by one Party (the "Disclosing Party") to the other Party (the "Recipient") relating to the Research Project that (i) is in writing designated "confidential" (or with word of similar import) at the time of disclosure; (ii) if disclosed orally, visually, or physically, is designated "confidential" (or with word of similar import) at the time of disclosure; or (iii) a reasonable person would consider confidential based on the nature of such information and the circumstances of disclosure. "Confidential Information" shall not include:

A. Information that is known to the Recipient or independently developed by Recipient without use of the Disclosing Party's Confidential Information, in each case, to the extent evidenced by written records;

B. Information the Recipient can show was rightfully received by the Recipient from a third

party having no obligation of confidentiality to the Disclosing Party at the time of disclosure;

C. Information that becomes patented, published, or otherwise part of the public domain other than as a result of a breach by the Recipient of its obligations hereunder; or

D. Information that is required to be disclosed by order of United States governmental authority, law, rule of court, regulation, subpoena, or a court of competent jurisdiction; provided that the Recipient shall use reasonable efforts to obtain confidential treatment of such information by such authority or court.

1.4 "Joint Intellectual Property" means any and all inventions, discoveries, works of authorship (including computer software) and copyrighted materials that are created, conceived, discovered, or reduced to practice jointly by employees of both CHOP and Sponsor, or solely by employees of Sponsor using facilities, equipment, funds or other resources of CHOP, during the performance of the Research Project.

1.5 "Materials" means any and all materials, including, but not limited to, any and all chemical compounds, biological materials, and any additional progeny and unmodified derivatives of such material, supplied by Sponsor to CHOP, as further described in the Research Project.

1.6 "Principal Investigator" means Beverly Davidson, PhD, who has agreed to serve as principal investigator for the Research Project on behalf of CHOP, and who shall be responsible for the administration and supervision of the Research Project.

1.7 "Research Project" means the research project described in Appendix A to this Agreement, which is attached hereto and made a part hereof.

1.8 "Results" mean all experimental data, analyses, and results arising from the performance of the Research Project.

1.9 "Sponsor Intellectual Property" means any and all inventions, discoveries, materials, works of authorship (including computer software) and copyrighted materials that are created, conceived, discovered or reduced to practice solely by employees of Sponsor during the performance of the Research Project and through no use of facilities, equipment, funds or other resources of CHOP.

1.10 "Sponsor Liaison" means Marlene Modi, PhD, who shall be the designated Sponsor representative with respect to any discussions regarding the activities under this Agreement.

ARTICLE 2: RESEARCH PROJECT

2.1 Conduct of Research Project. CHOP shall commence the Research Project promptly after the Effective Date of this Agreement and upon payment by Sponsor of any funds owed pursuant to Article 4 herein, and shall use reasonable efforts to conduct such Research Project in accordance with the terms and conditions of this Agreement. Sponsor acknowledges that CHOP and the Principal Investigator shall have the freedom to conduct and supervise the Research Project in a manner consistent with CHOP's research, educational, and patient care mission, and further acknowledges that CHOP and the Principal Investigator do not guarantee any specific research results of the Research Project. This Agreement shall not be construed to limit the freedom of individuals participating in the Research Project to engage in any other research, however funded.

2.2 Principal Investigator. If the services of the Principal Investigator become unavailable to CHOP for any reason, CHOP shall be entitled to designate another CHOP researcher who is acceptable to both Parties to serve as the Principal Investigator of the Research Project. If a substitute Principal Investigator has not been designated within sixty (60) days after the original Principal Investigator ceases his/her services under this Agreement, either Party may terminate this Agreement upon written notice thereof to the other Party, subject to the provisions of Article 9 hereof.

2.3 Research Results. CHOP shall periodically report to the Sponsor Liaison a summary of Results on a confidential basis. During and following the Research Project, CHOP owns all Results and corresponding summaries as provided hereunder. For the avoidance of doubt, CHOP Intellectual Property and Joint Intellectual Property shall not be considered Results. Additionally, CHOP will retain ownership of all research notes and notebooks. CHOP grants to Sponsor a royalty-free, non-exclusive, non-transferrable (except by Qualified Assignment as that term is defined in the License Agreement), irrevocable license to use the Results for all purposes.

2.4 Materials Transfer. The Materials that may be received by CHOP from Sponsor are limited to those Materials manufactured by CHOP and sold by CHOP to Sponsor. Any such Materials received by CHOP shall be used subject to the following conditions:

A. The Materials are to be used solely for the Research Project, and only by the Principal Investigator or Sponsor Liaison, and those employees under his/her supervision;
B. The Materials will be used in accordance with all applicable statutes, regulations, and Federal Government guidelines;
C. No further use or transfer of the Materials is permitted without the prior written permission of the owning Party;
D. The source, composition, and any proprietary information about of the Materials may not be publicly disclosed by CHOP without Sponsor's prior written consent; and
E. At the completion of the Research Project, or its earlier termination, and upon written request by Sponsor, the Materials shall be returned to the Sponsor or destroyed.

ARTICLE 3: TERM OF AGREEMENT

3.1 Term. The initial term of this Agreement shall begin on the Effective Date and shall continue for a period of eighteen (18) months, unless terminated sooner pursuant to Articles 2.2 or 9 hereof. This Agreement may be extended or renewed only by the Parties' mutual written agreement, which shall be an amendment to this Agreement, in accordance with Article 11.6.

ARTICLE 4: COMPENSATION

4.1 Compensation. Sponsor shall pay CHOP an amount not to exceed $263,704 (the "Project Amount"), which represents all direct and indirect costs of the Research Project as set forth in the budget in Appendix B attached hereto and made a part hereof. Sponsor acknowledges that this budget is a good faith estimate only and not a guarantee of the cost to conduct the Research Project.

4.2 Timing of Payments. Sponsor agrees to make payments to CHOP in accordance with the payment schedule set forth in Appendix B, and within thirty (30) days of transmission of a related invoice

by CHOP to Sponsor. Invoices shall be sent by CHOP to jason.slakter@orphiontherapeutics.com. All payments are to be made by check, payable in United States dollars, to "The Children's Hospital of Philadelphia," should identify Sponsor and Principal Investigator, and be sent to

The Children's Hospital of Philadelphia
Lockbox # 1457
PO Box 8500
Philadelphia, PA 19178-1457

4.3 Record Keeping. CHOP shall maintain accurate records and books of account relating to this Agreement in accordance with accepted accounting practices to ensure that funds provided by Sponsor are spent in accordance with this Agreement, provided, however, that CHOP may rebudget funds between cost categories (other than general overhead) as deemed necessary by CHOP and Principal Investigator. CHOP shall notify Sponsor in writing of any material changes to the budget. CHOP shall make such records and books available to Sponsor upon reasonable advance written notice and at Sponsor's expense during CHOP's normal business hours, under conditions of confidentiality, but not more frequently than once each calendar year.

4.4 Title to Equipment. Sponsor agrees that title to any equipment, laboratory animals, or any other supplies (other than the Materials) made or acquired with funds provided under this Agreement shall vest in CHOP, and such equipment, animals, or supplies shall remain the property of CHOP following the conclusion or termination of this Agreement. CHOP will be responsible, at CHOP's sole expense, for the disposal or maintenance of any such equipment, laboratory animals, or any other supplies following the conclusion or termination of this Agreement.

4.5 Residual Funds. Any unexpended or other funds remaining at the conclusion of this Agreement shall be returned to Sponsor.

ARTICLE 5: INTELLECTUAL PROPERTY

5.1 Background Intellectual Property. Unless otherwise specified herein, each Party shall retain all rights to its respective Background Intellectual Property, and nothing in this Agreement shall confer any right to one Party to acquire ownership of, or a license to, the other Party's Background Intellectual Property. Notwithstanding the foregoing, the Parties acknowledge that CHOP has licensed certain Background Intellectual Property to Sponsor pursuant to the License Agreement, and such Background Intellectual Property constitutes Licensed Patent Rights thereunder.

5.2 Ownership of Research Project Intellectual Property. CHOP shall be the sole owner of any CHOP Intellectual Property. Sponsor shall be the sole owner of any Sponsor Intellectual Property. CHOP and Sponsor shall be joint owners of any Joint Intellectual Property. Both CHOP and Sponsor agree to execute any documentation necessary to convey and/or formalize the Parties' undivided co-ownership rights in the Joint Intellectual Property.

5.3 Disclosure. CHOP agrees to provide to Sponsor a written disclosure of any CHOP Intellectual Property and Joint Intellectual Property considered protectable by intellectual property laws in the U.S., which disclosure shall be made in a manner consistent with preservation of intellectual property rights. Such intellectual property shall be considered "Future CHOP IP" or "Future CHOP

Know-How" as defined in the License Agreement. Sponsor shall similarly disclose to CHOP any Sponsor Intellectual Property and Joint Intellectual Property considered protectable by intellectual property laws in the U.S.

5.4 Review Period. Sponsor agrees to advise CHOP in writing, no later than thirty (30) days after the date of such disclosure, whether it requests CHOP to file and prosecute patent applications related to such CHOP Intellectual Property or Joint Intellectual Property. Sponsor agrees to reimburse CHOP for all documented expenses, including, but not limited to, legal fees, filing and maintenance fees, and other governmental charges incurred in connection with the preparation, filing, and prosecution of the patent applications and maintenance of the patents that Sponsor requested CHOP to file and prosecute. If Sponsor requests CHOP to file and prosecute patent applications related to such CHOP Intellectual Property or Joint Intellectual Property, such CHOP Intellectual Property or Joint Intellectual Property shall immediately and automatically become Licensed Patent Rights under the License Agreement and shall be immediately and automatically added to Appendix A of the License Agreement and become subject to the terms and conditions of the License Agreement. If Sponsor does not request CHOP to file and prosecute any patent applications on CHOP Intellectual Property, CHOP may proceed with such preparation and prosecution of CHOP Intellectual Property at its own expense, but such patent applications shall be excluded from the License Agreement.

ARTICLE 6: LICENSE RIGHTS

6.1 Reciprocal Licenses. Each Party agrees to grant the other a royalty-free, non-exclusive license to use CHOP Intellectual Property or Sponsor Intellectual Property (as the case may be) for internal non-commercial purposes only.

6.2 Federal Government Rights. Any license granted to Sponsor pursuant to this Agreement or the License Agreement shall be subject, if applicable, to the rights of the United States government reserved under Public Laws 96-517, 97-256 and 98-620, codified at 35 U.S.C. 200-212, and any regulations issued thereunder as may be amended from time to time. Any right granted in this Agreement greater than that permitted under applicable Federal law and policy shall be modified as may be required to conform to such Federal law or policy.

ARTICLE 7: CONFIDENTIALITY

7.1 Obligations. Each Party agrees to maintain in confidence, and to not disclose to any third party, any Confidential Information of the other Party received pursuant to this Agreement. Each Party agrees to ensure that its employees have access to the other Party's Confidential Information only on a need-to-know basis, and that such employees are bound by the obligations hereunder.

7.2 Duration of Obligations. The Parties' obligations concerning nondisclosure and non-use of Confidential Information received under this Agreement shall continue for five (5) years from the conclusion or early termination of this Agreement.

ARTICLE 8: PUBLICATION, USE OF NAME

8.1 Right to Publish. Sponsor acknowledges that the basic objective of research activities at CHOP is the generation of new knowledge and its expeditious dissemination. To further that objective, CHOP retains the right, at its discretion, to demonstrate, publish, or publicize the Results, subject to the provisions of Article 8.2 hereof.

8.2 Publication Submission. Should CHOP desire to disclose the Results publicly, in writing or by oral presentation, CHOP shall notify Sponsor in writing of CHOP's intention at least thirty (30) days before such disclosure. CHOP shall include with such notice a description of the oral presentation, or, in the case of a manuscript or other proposed written disclosure, a current draft of such written disclosure. Sponsor shall have thirty (30) days from receipt of the manuscript to present any written comments to CHOP, and such comments shall be given due consideration by CHOP. The publication of the Results may be delayed at Sponsor's written request for a period up to an additional thirty (30) days if it contains a disclosure of any invention(s) on which either Party desires to file a United States or foreign patent application or an application or registration for any other type of intellectual property protection. All such filings are subject to the provisions of Article 5 herein. No right of Sponsor approval of publications is implied by this article.

8.3 Publicity. Neither Party shall use the name, insignia, trademark, trade name, logo, abbreviation, nickname, or other identifying mark or term of the other Party for any purpose, except as required by law, without the prior written consent of the other Party, provided, however, that CHOP may use the name of Sponsor in its routine listings of sponsored projects, as required on grant applications, and as required by scientific journals for publication. In the case of CHOP, Sponsor shall obtain the prior written approval of CHOP's Chief Marketing Officer for each instance of use, and such requests shall be made to CHOP's Office of General Counsel at legal@email.chop.edu.

ARTICLE 9: TERMINATION

9.1 Termination for Cause. In addition to the termination right set forth in Article 2.2 hereof, either Party may terminate this Agreement, effective upon written notice to the other Party, if the other Party breaches any of the material terms or conditions of this Agreement and fails to cure such material breach within thirty (30) days after receiving written notice thereof; *provided, however*, that if cure is not capable of being completed within such 30 day period, but the breaching Party has taken steps during such 30 day period, the cure period shall be extended for another 30 days.

9.2 Effect of Termination. In the event of termination of this Agreement prior to its stated term, whether for breach or for any other reason whatsoever, CHOP shall be entitled to the Project Amount incurred through the effective date of termination, and the full cost of each student and faculty member supported hereunder through the end of such commitments, less payments already made by Sponsor to CHOP under this Agreement.

9.3 Survivability. Termination of this Agreement shall not affect the rights and obligations of the Parties accrued prior to termination hereof. The provisions of Article 5, entitled "Intellectual Property"; Article 7, entitled "Confidentiality"; Article 10, entitled "Disclaimer of Warranties, Indemnification"; this Article 9, entitled "Termination"; and Article 11, entitled "Additional Provisions" shall survive such termination consistent with any timeframes noted therein.

ARTICLE 10: DISCLAIMER OF WARRANTIES, INDEMNIFICATION

10.1. NO WARRANTIES. EXCEPT AS PROVIDED UNDER THIS ARTICLE, CHOP MAKES NO WARRANTIES, EXPRESS OR IMPLIED, AS TO ANY MATTER WHATSOEVER, INCLUDING, WITHOUT LIMITATION, WARRANTIES WITH RESPECT TO THE CONDUCT, COMPLETION, SUCCESS, OR PARTICULAR RESULTS OF THE RESEARCH PROJECT, OR THE CONDITION OF ANY INVENTION(S), PRODUCTS(S),

OR DELIVERABLE(S) WHETHER TANGIBLE OR INTANGIBLE, CONCEIVED, DISCOVERED, OR DEVELOPED UNDER THIS AGREEMENT, OR THE OWNERSHIP, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE OF THE RESEARCH PROJECT, OR ANY SUCH INVENTION(S), PRODUCT(S), OR DELIVERABLE(S). FURTHER, CHOP MAKES NO EXPRESS OR IMPLIED WARRANTY THAT THE USE OF ANY INVENTION(S), PRODUCT(S), OR DELIVERABLE(S) WILL NOT INFRINGE ANY PATENT OR OTHER PROPRIETARY RIGHTS. NEITHER PARTY =SHALL BE LIABLE FOR ANY INDIRECT, SPECIAL, CONSEQUENTIAL, PUNITIVE, OR OTHER DAMAGES SUFFERED BY THE OTHER PARTY OR ANY OTHER PERSON RESULTING FROM THE RESEARCH PROJECT OR THE USE OF ANY SUCH INVENTION(S), PRODUCT(S), OR DELIVERABLE(S) OR THE MATERIALS.

10.2 Representations and Warranties of CHOP. CHOP hereby represents and warrants to Sponsor that the official signing this Agreement has the authority to do so.

10.3 Representation and Warranties of Sponsor. Sponsor hereby represents and warrants to CHOP that the official signing this Agreement has the authority to do so. Sponsor further represents that it is financially able to satisfy any funding commitments made in Appendix B.

10.4 Indemnification. Sponsor agrees to indemnify and hold harmless CHOP, the Principal Investigator, and any of CHOP's trustees, officers, medical staff, research staff, employees, affiliates, and agents, and their respective heirs and assigns (hereinafter referred to collectively as the "Indemnified Parties"), from and against any and all liability, claims, lawsuits, losses, damages, costs, or expenses (including attorneys' fees and costs of litigation incurred by CHOP to defend against such claims) (collectively, "Claims")that the Indemnified Parties may hereafter incur, suffer, or be required to pay as a result of Sponsor's use of the Results, or any CHOP Intellectual Property, or any Joint Intellectual Property, or as a result of any breach of this Agreement, or any wrongful act or omission of Sponsor, its employees, affiliates, contractors, licensees, or agents other than any such Claims that are due to an Indemnified Parties' negligence or willful misconduct. CHOP shall notify Sponsor upon learning of the institution or threatened institution of any such liability, claims, lawsuits, losses, damages, costs, and expenses.

10. 5 Insurance. Sponsor represents and warrants that it shall maintain commercial general liability insurance in amounts sufficient to cover its indemnification obligations in Article 10.4. Sponsor shall provide CHOP with written evidence of such insurance upon request. Sponsor shall provide CHOP with written notice at least thirty (30) days prior to the cancellation, non-renewal, or material change in such insurance; if the Sponsor does not obtain replacement insurance providing comparable coverage within a thirty (30) day period, CHOP shall have the right to terminate this Agreement effective at the end of the thirty (30) day period without notice or any additional waiting period.

10.6 LIMITATION OF LIABILITY. THE MAXIMUM LIABILITY OF CHOP TO SPONSOR OR ANY INDEMNIFIED PARTY SHALL NOT EXCEED THE FEES PAID TO CHOP UNDER THIS AGREEMENT. IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY OR AN INDEMNIFIED PARTY FOR ANY SPECIAL, INDIRECT, EXEMPLARY, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, INCLUDING, BUT NOT LIMITED TO, ANY DAMAGES RESULTING FROM LOSS OF DATA, DELAY IN THE RESEARCH, LOSS OF PROFITS, OR LOSS OF BUSINESS ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT OR ANY PRODUCTS, SERVICES, OR MATERIAL FURNISHED HEREUNDER, EVEN IF CHOP HAS BEEN ADVISED OR SHOULD KNOW OF THE POSSIBLILITY OF SUCH DAMAGES.

EXCEPT AS EXPRESSLY STATED TO THE CONTRARY, THE LIMITATIONS STATED ABOVE SHALL APPLY WHETHER THE ASSERTED CLAIM, LIABILITY, OR DAMAGES ARE BASED ON CONTRACT (INCLUDING, BUT NOT LIMITED TO, BREACH OF WARRANTY), TORT (INCLUDING, BUT NOT LIMITED TO, NEGLIGENCE AND STRICT LIABILITY) OR ANY OTHER LEGAL OR EQUITABLE GROUNDS, AND REGARDLESS OF WHETHER THE ASSERTED CLAIM, LIABILITY, OR DAMAGES ARISE FROM PERSONAL INJURY, PROPERTY DAMAGE, ECONOMIC LOSS, OR ANY OTHER KIND OF INJURY LOSS OR DAMAGE. EACH OF SUCH LIMITATION IS INTENDED TO BE ENFORECABLE REGARDLESS OF WHETHER ANY OTHER EXCLUSIVE OR NON-EXCLUSIVE REMEDY UNDER THIS AGREEMENT FAILS OF ITS ESSENTIAL PURPOSE.

FURTHER, THE PARTIES ACKNOWLEDGE THAT THE FEES PAID TO CHOP FOR RESEARCH PROJECT UNDER THIS AGREEMENT REFLECT THE ALLOCATION OF RISKS AND THE LIMITATIONS OF EACH PARTY'S LIABILITY HEREUNDER.

ARTICLE 11: ADDITIONAL PROVISIONS

11.1 Governing Law & Dispute Resolution. This Agreement shall be governed by the laws of the Commonwealth of Pennsylvania without regard to conflicts of law principles. In the event that a Party to this Agreement perceives the existence of a dispute with the other Party concerning any right or duty provided for herein, the Parties shall, as soon as practicable, confer in an attempt to resolve the dispute. If the Parties are unable to resolve such dispute amicably, then the Parties hereby submit to the sole and exclusive jurisdiction in the Commonwealth of Pennsylvania courts located in Philadelphia County, or the federal courts located within the Eastern District of Pennsylvania, with respect to any and all disputes concerning the subject of this Agreement.

11.2 No Assignment. No rights hereunder may be assigned by Sponsor, directly or by merger or other operation of law, without the express written consent of CHOP, unless it is deemed a "Qualified Assignment" as that term is defined in the License Agreement. Any prohibited assignment of this Agreement or the rights hereunder shall be null and void. No assignment shall relieve Sponsor of responsibility for the performance of any accrued obligations that it has prior to such assignment. This Agreement shall be binding upon and inure to the benefit of permitted assigns of Sponsor.

11.3 Waiver. A waiver by either Party of a breach or violation of this Agreement must be in writing. No delay or omission on the part of either Party to enforce or exercise any right under this Agreement shall operate as a waiver of that right or any other right hereunder, or the ability to later assert that right relative to the particular situation involved, or to terminate this Agreement rising out of any subsequent default or breach. A waiver by either Party of a breach or violation of any provision of this Agreement will not constitute or be construed as a waiver of any subsequent breach or violation of that provision, or as a waiver of any breach or violation of any other provision of this Agreement.

11.4 Independent Contractors. Nothing herein shall be deemed to establish a relationship of principal and agent between CHOP and Sponsor, nor any of their agents or employees for any purpose whatsoever. This Agreement shall not be construed as constituting CHOP and Sponsor as partners, or as creating any other form of legal association or arrangement that would impose liability upon one Party for the act or failure to act of the other Party. Neither Party shall have any authority to make any statements, representations, or commitments of any kind, or to take any action that shall be binding on the other Party, except as may be explicitly provided for herein or authorized

in writing.

11.5 Notices. Notices under this Agreement shall be in writing, sent by courier, and addressed as follows:

If to CHOP:

The Children's Hospital of Philadelphia
Roberts Center for Pediatric Research – 17th Floor
2716 South Street
Philadelphia, PA 19146
Attention: Office of Collaborative and Corporate Research Contracts

With a copy to:

The Children's Hospital of Philadelphia
Roberts Center for Pediatric Research – 20th Floor
2716 South Street
Philadelphia, PA 19146
Attn: Office of General Counsel

If to Sponsor:

Orphion Therapeutics, LLC
57 Meadow Woods Road
Great Neck, NY 11020
Attention: Jason S. Slakter, MD

Said notice shall be deemed to be given as of the date of mailing.

11.6 Entire Agreement. This Agreement embodies the entire understanding between the Parties and supersedes all prior understandings and agreements, whether written or oral, relating to the subject matter hereof. This Agreement may not be varied except by a written document signed by duly authorized representatives of both Parties.

11.7 Severability. Any of the provisions of this Agreement that are determined to be invalid or unenforceable in any jurisdiction shall be ineffective to the extent of such invalidity or unenforceability in such jurisdiction, without rendering invalid or unenforceable the remaining provisions hereof or affecting the validity or unenforceability of any of the terms of this Agreement in any other jurisdiction.

11.8 Headings. The headings and captions used in this Agreement are for convenience of reference only and shall not affect its construction or interpretation.

11.9 No Benefits. Nothing in this Agreement, express or implied, is intended to confer on any person other than the Parties hereto, or their permitted assigns, any benefits, rights, or remedies.

11.10 Force Majeure. Neither Party shall be liable for any failure to perform as required by this Agreement to the extent such failure to perform is due to circumstances reasonably beyond such Party's control, including, without limitation, labor disturbances or labor disputes of any kind, accidents, failure of any governmental approval required for full performance, civil disorders or commotions, acts of aggression, acts of God, energy or other conservation measures imposed by law or regulation, explosions, failure of utilities, mechanical breakdowns, material shortages, disease, or other such occurrences. In the event of the occurrence of such a force majeure event, the Party unable to perform shall promptly notify the other Party pursuant to Article 11.5. Each Party shall further use reasonable efforts to resume performance as quickly as possible, and shall suspend performance only for such period of time as is necessary as a result of the force majeure event. Due to the COVID-19 pandemic, CHOP has temporarily suspended certain of its research activities and the Parties have prepared the Research Project and Budget assuming that the Research Project will continue at a later date once sponsored research activities at CHOP resume regular operations. In addition, if the COVID-19 pandemic or any governmental action or CHOP action in response thereto (the "Pandemic") impairs or delays any portion of the Research Project, the Parties agree to cooperate in good faith to further amend the Research Project, Term, and/or Budget to address such impairment or delay. No payments shall be due or paid by Sponsor or accrued by CHOP under this Agreement until the Research Project is no longer suspended by CHOP due to the COVID-19 pandemic. Promptly following the end of each month, CHOP shall provide Sponsor with an invoice for any amounts then payable to CHOP based on the Budget. Notwithstanding anything to the contrary contained in this Agreement, the Budget, or any associated timelines, CHOP shall not bill for any research or services that are not performed during a particular month due exclusively to stoppages ordered by CHOP due to the Pandemic and unrelated to any actions of or by Sponsor

11.11 Export Controls. All rights granted to Sponsor by this Agreement are contingent upon compliance with United States laws and regulations controlling the export of technical data, computer software, laboratory prototypes, and all other export controlled commodities. These laws include, but are not limited to, the Arms Export Control Act and the Export Administration Act as they may be amended. Sponsor shall not, directly or indirectly, export any export controlled commodities that are subject to this Agreement, unless the required authorization and/or license is obtained from the proper government agency(ies) prior to export. By granting rights in this Agreement, CHOP does not represent that export authorization or an export license will not be necessary, or, if necessary, that such authorization or export license will be granted.

11.12 Counterparts. This Agreement may be executed in two or more counterparts, each of which will be deemed an original, and all of which together will constitute the same agreement. This Agreement may be executed by a Party through electronic means, and copies of this Agreement executed and delivered by means of electronic signatures shall have the same force and effect as if such signatures were originals. Delivery of an executed copy of this Agreement by any Party via electronic transmission will be as effective as delivery of a manually executed copy of the Agreement.

[SIGNATURE PAGE TO FOLLOW]

IN WITNESS WHEREOF, the duly authorized representatives of the Parties hereby execute this Agreement as of the date first written above.

THE CHILDREN'S HOSPITAL OF PHILADELPHIA

By: DocuSigned by: D1BB2EBCD134457... ___

Name: Charles Bartunek

Title: Director, Office of Collaborative & Corporate Research Contracts

Date: 10/14/2020

SPONSOR

By: DocuSigned by: Jason Slakter 03E939FF5D7641B... _____

Name: Jason S. Slakter, MD

Title: CEO

Date: 10/13/2020

Read and acknowledged
PRINCIPAL INVESTIGATOR:

By: DocuSigned by: 2EB7E59A4D62491... _____

Name: Beverly Davidson

Date: 10/14/2020

Appendix A

RESEARCH PROJECT DESCRIPTION

Finalization of two nonclinical (monkey) biodistribution study reports and/or amendments (ie., CRL_MPI 2680-003, "Subretinal Dose Range Finding Study of AAV2-TPP1 in Monkeys" and "TPP1 Retinal NHP Study #2_CHOP") and related activities which meet health authority requirements:

--perform TPP1 assay work for fluids and tissues collected in two above studies,
--perform qPCR for viral vector assay work for fluids and tissues collected in two above studies,
--provide Bioanalytical sub-reports (related to above assay work which includes but is not limited to raw data regarding assay methods, assay performance parameters and assay results),
--make contributions to study reports and sub-reports working with Marlene Modi,
--coordinate contribution to study reports of CHOP personnel (eg, veterinarian staff),
--provide transfer of responsibility letter to CRL, Mattawan WI from CHOP to Orphion for study CRL-MPI 2680-003,
--ensure appropriate signatures from CHOP contributors are included in finalized study reports and amendments,
--ensure all protocol-specified activities are accounted for in the study reports and amendments,
--provide an archival package to Orphion for both studies of sufficient quality to meet health authority requirements.

Note: these are tasks that must be completed and with study reports as the final deliverables that are acceptable to world-wide health authorities.

Appendix B

BUDGET

Direct Costs: $149,832
Indirect Costs: $113,872
Total Costs: $263,704

Invoice and Payment Schedule

Date Payment Due	Amount of Payment Due
1. Within ten (10) days of Effective Date	1. 40%
2. Six (6) months after Effective Date	2. 30%
3. Completion of Research Project	3. 30%

EXHIBIT C

RESEARCH SERVICE AGREEMENT
FOR VECTOR PRODUCTION

THIS RESEARCH SERVICE AGREEMENT FOR VECTOR PRODUCTION (this "**Agreement**"), dated as of and made effective on last day written on the signature page below (the "**Effective Date**"), by and between The Children's Hospital of Philadelphia, a Pennsylvania nonprofit corporation, located at 3401 Civic Center Boulevard, Philadelphia, Pennsylvania 19104 (hereinafter called "**CHOP**") and Orphion Therapeutics, Inc., a Delaware corporation, having its registered office at 57 Meadow Woods Road, Great Neck, NY 11020 (hereinafter called "**Customer**"). Each of CHOP and Customer may be referred to herein as a "**party**" and, collectively, the "**parties**."

WHEREAS, CHOP, through its Clinical Vector Core ("**CVC**"), located within the Center for Cellular and Molecular Therapeutics, has valuable experience, skill, and ability in relation to the research described in **Exhibit A** (the "**Project**");

WHEREAS, the performance of the Project is of mutual interest to Customer and CHOP and is consistent with CHOP's mission in research to develop scientific and medical knowledge to advance the state of patient care, with a particular focus on issues involving the care of children, and such Project is consistent with CHOP's status as a nonprofit educational healthcare institution;

WHEREAS, because of its specialized expertise in scientific research, CHOP is one of the only locations where the Project can be undertaken in a prompt and efficient manner in connection with CHOP's existing research activities; and

WHEREAS, CHOP will use scientifically reasonable efforts to perform the Project.

NOW THEREFORE, for good and valuable consideration the sufficiency of which is expressly acknowledged, the undersigned parties, intending to be legally bound, mutually agree as follows:

1. ***Scope of Work.***

1.1 *Project Deliverables.* CHOP will undertake the Project, as more fully described in **Exhibit A** which is hereby incorporated into and made part of this Agreement in accordance with the applicable Statement of Work, generally prevailing research standards, and applicable laws and regulations, including with respect to any processing of materials as required for the Project Deliverables. **Exhibit A** and one or more Statements of Work ("**SOW**") shall set forth all deliverables required pursuant to this Project (the "**Project Deliverables**"). It is agreed that **Exhibit A** will govern the direction of the Project until amended in a signed writing by authorized representatives of Customer and CHOP. The Project shall be under the direction of the Director of the Clinical Vector Core, a CHOP employee. CHOP represents and warrants that it has the appropriately qualified and experienced staff and the necessary equipment and experience in order to perform its activities hereunder in accordance with the terms of this Agreement, none of CHOP's employees providing services under this Agreement have been debarred or disqualified by any regulatory authority or under any applicable laws or regulations, and CHOP will not use in any capacity in connection with this Agreement the services of any such individual. The Project Deliverables and the materials included therein are provided to Customer for use only for preclinical or nonclinical purposes (e.g., analytical development, in vitro or lab animal studies, toxicology studies, research and development). If Customer is unable to provide requested documentation and materials necessary to initiate the Project at the agreed upon start date, CHOP will reserve the right to re-schedule.

1.2 *Sale of Materials*. On the terms and subject to the conditions set forth in this Agreement, effective immediately following CHOP's provision of the Project Deliverables to Customer, CHOP hereby sells, assigns,

transfers, and conveys to Customer, and Customer hereby acquires, accepts, and purchases from CHOP, all of CHOP's right, title and interest in the Project Deliverables. CHOP shall deliver or cause to be delivered to Customer the Project Deliverables as described in **Exhibit A** or as further agreed in writing between CHOP and Customer during the Term of this Agreement to such location set forth in **Exhibit A** or otherwise agreed to by the Parties in writing.

1.3 *Restriction from Commercial Purposes.*

(A) Project Deliverables shall not be provided to any entity to be used (or provided to a third party for use) for any commercial purposes. As used herein "**Commercial Purposes**" shall mean any sale, lease, license (or exercise of an option right to acquire a license), or assignment granting commercial rights in or to any of the Project Deliverables (or any material included therein), by or to any for-profit or commercial entity, or any use to perform contract research, screen compound libraries, or to produce or manufacture any products for sale, or to conduct research activities that result in any sale, lease, license (or exercise of an option right to acquire a license), or assignment granting commercial rights in or to any Project Deliverables (or material included therein) by or to any for-profit or commercial entity. For clarity, the conduct of industry-sponsored academic research shall not be deemed to be Commercial Purposes *per se* unless any of the above conditions of this definition are met.

(B) Customer represents and warrants that it will immediately advise CHOP of any use or activity that would cause CHOP's manufacture of the Project Deliverables hereunder to be a manufacture for any Commercial Purposes as defined herein and CHOP reserves the right to immediately suspend or terminate all such manufacturing activities until such time as the appropriate license agreements are put in place to permit use for such Commercial Purposes.

1.4 *Reserved.*

1.5 *Pre-clinical or Non-Clinical-Grade Product.* In the event that CHOP manufactures Project Deliverables for use in non-human studies, Customer acknowledges that the Project Deliverables are, except as may be expressly provided herein or in any SOW, provided "as is", and Customer agrees that such Project Deliverables shall not be used in humans or for any purpose including but not limited to any diagnostic, prognostic, or treatment purposes.

1.6 *Customer Delays*. If delays in performance of the Project under any SOW are experienced because of Customer's failure to supply CHOP with Customer Material, or information required to perform the Project, CHOP shall be entitled, in each case without penalty to CHOP, to (a) reallocate resources otherwise reserved for the performance of the Project and/or (b) extend the timelines for completion of the Project under the relevant SOW. Any required changes to the SOW will be expressed in a writing. Failure of the parties to execute a writing will result in a deemed termination of the SOW by the Customer without cause pursuant to Section 2 below.

2. *Customer Responsibilities*.

2.1 *Customer Material*. Customer hereby agrees that in addition to the rights and obligations set forth herein, Customer shall also assume the responsibilities and obligations set forth in the CHOP Sponsor/IND Holder: Authorities and Responsibilities Policy 026 ("**QMP 026**"), attached hereto as **Exhibit B** and which is hereby incorporated and made part of this Agreement and which may be amended from time to time. CHOP may revise and change QMP 026 at its sole discretion, and after any such change, CHOP will notify Customer in accordance with the notice terms set forth herein.

2.2 *Customer Material Specifications.* Customer material, if any, to be provided by Customer to CHOP ("**Customer Material**") shall be expressly identified in **Exhibit B**, shall be manufactured and otherwise

processed in accordance with CHOP standards and specifications set forth in **Exhibit B** and shall be of sufficient quantity for CHOP to provide the Project Deliverables, and include required documentation, as described in QMP 026. Customer agrees and expressly understands that CHOP will not confirm the sequence of the Customer Material nor be responsible for nor assume any liability for the quality of the Customer Material. In addition, Customer shall approve in writing the CVC as a suitable manufacturer and confirm the quality system to be compliant with applicable regulations, cGMP standards and guidelines as applicable to the product. Customer understands and agrees that Customer is responsible for developing, qualifying, and conducting an appropriate potency-indicating assay for the clinical product, and reporting test results to any regulators, and for developing, qualifying, and conducting, or outsourcing, any assay required but not offered as a qualified assay by the CVC and reporting test results to any regulators. Customer acknowledges and agrees to accept full responsibility for the clinical use (if any) of the Customer Material provided to CHOP, distribution, tracking, reporting, and drug recall (as applicable).

2.3 Reserved.

3. *Term and Termination.*

3.1 *Term.* The term of this Agreement will commence on the Effective Date and will continue until the third (3rd) anniversary of the Effective Date unless terminated prior to that time or extended by the parties (the "**Term**"). After the Term, this Agreement shall automatically renew for successive one (1) year terms unless or until the parties agree otherwise in writing.

3.2 *Termination.* Either party may terminate this Agreement by written notice to the other party for any material breach of this Agreement by the other party, if such breach is not cured within thirty (30) days after the breaching party receives written notice of such breach from the non-breaching party; provided, however, that if such breach is not capable of being cured within such thirty-day period and the breaching party has commenced and diligently continued actions to cure such breach within such thirty-day period, except in the case of a payment default, the cure period shall be extended to ninety (90) days, so long as the breaching party is making diligent efforts to do so. Such termination shall be effective upon expiration of such cure period. If terminated by Customer, CHOP is entitled to full payment for all reasonable, actually incurred costs and reasonable non-cancelable and non-refundable commitments incurred as of the effective date of the termination and Customer shall pay such payment to CHOP upon notice by CHOP. For the avoidance of doubt Customer shall not be entitled to return the Down Payment (as defined herein).

3.3 *Termination Without Cause.* Either party may terminate this Agreement by providing written notice of termination no less than ninety (90) days in advance of the date of termination for any reason.

3.4 *Termination by Insolvency*. Either party may terminate this Agreement upon notice to the other party, upon (a) the dissolution, termination of existence, liquidation or business failure of the other party; (b) the appointment of a custodian or receiver for the other party who has not been terminated or dismissed within ninety (90) days of such appointment; (c) the institution by the other party of any proceeding under national, federal or state bankruptcy, reorganization, receivership, or other similar laws affecting the rights of creditors generally or the making by such party of a composition or any assignment for the benefit of creditors under any national, federal or state bankruptcy, reorganization, receivership, or other similar law affecting the rights of creditors generally, which proceeding is not dismissed within ninety (90) days of filing. All rights and licenses granted pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11 of the United States Code, licenses of rights of "intellectual property" as defined therein.

4. Costs and Payment.

4.1 *Costs Set Forth in SOW.* As full and complete consideration for CHOP's performance under this Agreement, Customer will pay CHOP the amount specified in the agreed upon SOW. This includes, but is not

limited to, the costs of labor, materials, QC testing, equipment maintenance, fill/finish manufacturing or processes, stability testing, insurance, chemistry, manufacturing controls ("**CMC**") support, and shipping & handling (in each case, as applicable). A certificate of analysis ("**CoA**") or certificate of characterization ("**CoC**") documenting purity, titer, and safety for GMP-grade and non-GMP grade products, respectively, will be provided at the completion of services (if applicable). Any additional costs need to be mutually agreed upon in writing between the parties.

4.2 *Payments and Down Payment.* Customer shall make payment to CHOP within thirty (30) days of receipt of an invoice under any SOW unless otherwise agreed to by the parties in writing. An initial invoice for one third (1/3) or thirty-three percent (33%) of the total cost of the Project will be processed upon CHOP's receipt of Customer's signed acceptance of each SOW under this Agreement. The amount due under such initial invoice shall be paid by Customer to CHOP and the parties agree that such amount shall be a non-refundable down-payment towards the cost of the Project (the "**Down Payment**").

4.3 *Liquidated Damages.* The parties hereto acknowledge and agree that in the event of a breach or cancelation of this Agreement by Customer the sums payable as the Down Payment shall give rise to liquidated damages and not penalties. The parties further acknowledge that (a) the amount of loss or damages likely to be incurred by CHOP is incapable or is difficult to precisely estimate, (b) the amounts specified bear a reasonable proportion and are not plainly or grossly disproportionate to the probable loss likely to be incurred by CHOP, and (c) the parties are sophisticated business parties and have been represented by sophisticated and able legal and financial counsel and negotiated this Agreement at arm's length.

4.4 *Remaining Balances.* The remaining balance due and amounts owed for the Project Deliverables under each SOW shall be due in accordance with the amounts and payment schedule agreed to by the parties under the "Payment Schedule" heading in each SOW.

4.5 *Additional Services, Late Payments, and Interest*. For any additional services, Customer will be invoiced for each service, as defined in the SOW. If Customer fails to make any payment due to CHOP under this Agreement by the due date for payment, then, without limiting the CHOP's remedies under this Agreement, including any liquidated damages due under this Agreement, CHOP may charge interest on the overdue amount at the rate of 2% per annum above the U.S. Federal Reserve Bank's prime rate from time to time. Such interest shall accrue on a daily basis from the due date until actual payment of the overdue amount, whether before or after judgment. Customer shall pay the interest together with any overdue amount. If the Project Deliverables do not meet the specifications listed in Appendix B, the parties shall meet to resolve any deficiencies, and, if the parties, acting in good faith, are unable to resolve any deficiencies within a reasonable period of time then, CHOP at its option may either cure any deficiencies or alternatively CHOP may provide a refund. For the avoidance of doubt Customer shall not be entitled to return or refund of the Down Payment.

5. Customer Reports to CHOP.

5.1 *Reserved*.

5.2 *Reserved*

6. Indemnities and Insurance.

6.1 *Customer Assumes Risk*. Customer assumes the risk of any damage, loss, or expense associated with or resulting from any of the following: (A) CHOP's transfer of the Project Deliverables to Customer using the transfer method of Customer's choosing; (B) Customer's conduct of any form of research utilizing the Project Deliverables; (C) Customer's use, handling, study, storage, return, or disposal of the Project Deliverables; (D) Customer's breach of this Agreement; or (E) Customer's failure to conform to law or regulation

applicable to this Agreement or the subject matter thereof, to the Project Deliverables, or to any research or activity conducted by Customer involving the Project Deliverables.

a) *Indemnification*. Customer shall indemnify, defend, advance and hold harmless CHOP and its officers, trustees, employees, members of its medical and research staff and agents (collectively "**CHOP Indemnitees**") from any claim, loss, judgment, liability, damage, settlement, fine or expense of any kind whatsoever (including reasonable attorneys' fees, interest, penalties and costs) (a "**Claim**") arising from: (A) CHOP's transfer of the Project Deliverables to Customer using the transfer method of Customer's choosing; (B) Customer's conduct of any research, including, without limitation, any human clinical trials, in any form utilizing the Project Deliverables; (C) Customer's use, handling, study, storage, return, or disposal of the Project Deliverables; (D) Customer's negligence or willful misconduct or any breach by Customer of this Agreement; or (E) Customer's failure to conform to law or regulation applicable to (1) this Agreement or the subject matter hereof, (2) to the Project Deliverables, or (3) to any research, including, without limitation, any human clinical trials or other activity conducted by Customer involving the Project Deliverables provided, however, that to the extent that any such Claim results solely from the gross negligence or willful or intentional misconduct of a CHOP Indemnitee, Customer shall have no such indemnity obligation with respect to any such CHOP Indemnitee.

6.2 *Indemnification Procedure.* To the extent reasonably feasible, CHOP shall notify Customer in writing of any Claim that, in CHOP's reasonable judgment, is likely to lead to a claim for indemnification. Customer shall promptly assume the entire defense of such Claim following CHOP's written notice, and shall, promptly upon notice from CHOP of any prior expenses, reimburse any CHOP Indemnitee for any expenses, fees or costs incurred by any CHOP Indemnitee with respect to defense of such Claim prior to the date of Customer's assumption of the defense. Customer shall have the right to manage the defense and settlement of any Claim, except that (A) Customer shall consult with the affected CHOP Indemnitee regularly with respect to all material matters pertaining to the defense of any such Claim; (B) CHOP shall have the right to approve Customer's choice of counsel to defend any such Claim, which approval shall not be unreasonably withheld by CHOP and (C) Customer may not enter into any settlement on behalf of any CHOP Indemnitee without CHOP's prior written approval, which approval shall not be unreasonably withheld by CHOP. CHOP may not enter into any settlement of any such Claim as to which Customer has an obligation to indemnify CHOP without the written permission of Customer, which approval shall not be unreasonably withheld by Customer. CHOP shall use commercially reasonable efforts to cooperate with Customer in the defense of the Claim at Customer's sole expense. CHOP may hire its own counsel, at its own expense, to monitor the defense of any Claim in which case Customer shall use commercially reasonable efforts at its sole expense to cooperate with CHOP in the defense of the Claim by CHOP's selected counsel. CHOP and Customer may execute such mutually acceptable Confidentiality and Joint Defense Agreements to protect privileged materials as shall be usual and customary in such proceedings and as shall be requested in writing by either CHOP or Customer.

6.3 *No Warranty; Limitation of Liability*. Customer acknowledges that the Project Deliverables are experimental in nature and may have unknown characteristics, may carry infectious agents, or may be otherwise hazardous. Customer agrees that after satisfaction of any milestones set forth in **Exhibit A**, once the Project Deliverables are shipped to customer, the transaction contemplated hereby shall be final and Customer shall not be entitled to any return, exchange or refund (but-for any non-compliance with specifications, in which case Section 4.5 shall apply in relation thereto). THE PROJECT DELIVERABLES ARE PROVIDED "AS IS" AND CHOP (INCLUDING THE CHOP INDEMNITEES) DISCLAIMS ANY WARRANTY, EXPRESS OR IMPLIED, WITH RESPECT TO THE PROJECT DELIVERABLES, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE OR ANY WARRANTY THAT THE USE OF THE PROJECT DELIVERABLES, BIOLOGICAL MATERIALS, ANALYTICAL METHODS, TESTING ASSAYS, SOPs, AND OTHER INFORMATION PROVIDED TO CUSTOMER WILL NOT INFRINGE OR VIOLATE ANY PATENT, COPYRIGHT, OR OTHER

PROPRIETARY RIGHT OF ANY THIRD PARTY. Without limitation of the foregoing, CHOP (including the CHOP Indemnitees) makes no representation or warranty as to the identity, purity, safety, fitness, or activity of the Project Deliverables except for the attributes as indicated on the CoA or CoC (as applicable). SUBJECT TO PAYMENT OBLIGATIONS SET FORTH IN SECTION 4 CUSTOMER'S EXCLUSIVE REMEDY UNDER THIS AGREEMENT IS, AT CHOP'S SOLE OPTION, A REFUND FOR THE PROJECT DELIVERABLES ACCORDING TO CUSTMER'S SPECIFICATIONS TO BE PROVIDED AT SUCH TIME (IF APPLICABLE). IN NO EVENT WILL ANY PARTY BE LIABLE FOR ANY CONSEQUENTIAL, INCIDENTAL, SPECIAL, OR INDIRECT DAMAGES, INCLUDING WITHOUT LIMITATION, DAMAGES FOR LOSS OF PROFITS, BUSINESS INTERRUPTION, LOSS OF BUSINESS INFORMATION, OR PROPERTY DAMAGE SUSTAINED BY CUSTOMER FROM THE USE OF, OR INABILITY TO USE, ANY PROJECT DELIVERABLES, EVEN IF THE PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. AS TO ANY LIABILITY NOT SUBJECT TO THE FOREGOING AND EXCLUDING THE INDEMNIFICATION OBLIGATIONS SET FORTH IN SECTION 6.2 AND SUBJECT TO PAYMENT OBLIGATIONS SET FORTH IN SECTION 4, A PARTY'S MAXIMUM LIABILITY WILL NOT EXCEED THE AGGREGATE AMOUNT PAID BY CUSTOMER TO CHOP FOR THE PROJECT DELIVERABLES. WITHOUT LIMITATION OF THE FOREGOING, NEITHER PARTY (INCLUDING ANY INDEMNITEES) MAKES ANY REPRESENTATION OR WARRANTY AS TO THE SAFETY, FITNESS, OR ACTIVITY OF THE PROJECT DELIVERABLES.

6.4 *Insurance.* Customer shall, at its own cost and expense, obtain and maintain in full force and effect during the Term of this Agreement the following: (A) Commercial General Liability Insurance with an amount of not less than three million dollars ($3,000,000) per occurrence and five million dollars ($5,000,0000) aggregate; (B) Clinical Trials Liability insurance with a per occurrence limit of not less than ten million dollars ($10,000,000); (C) Workers' Compensation Insurance with statutory limits and Employers Liability Insurance with limits of not less than $1,000,000 per accident; and (D) Auto Liability insurance for owned, hired and non-owned vehicles in a minimum amount of $1,000,000 combined single limit. Customer shall, at its own cost and expense, obtain and maintain in full force and effect during the Term, All Risk Property Insurance, including transit coverage, in an amount equal to the full replacement value of its property while in, or in transit to, a CHOP facility. Each party may self-insure all or any portion of the required insurance as long as, together with its affiliates, its US GAAP net worth is greater than one hundred million dollars ($100,000,000) or its annual EBITDA (earnings before interest, taxes, depreciation and amortization) is greater than seventy-five million dollars ($75,000,000). Each required insurance policy, other than self-insurance, shall be obtained from an insurance carrier with an A.M. Best rating of at least A- VII or an S&P rating of A. If any of the required policies of insurance are written on a claims made basis, such policies shall be maintained throughout the Term and for a period of at least five (5) years thereafter. Client shall obtain a waiver of subrogation clause from its property insurance carriers in favor of CHOP. Customer's Clinical Trials Liability insurance shall be primary and noncontributing with insurance, deductibles or self-insurance maintained by CHOP. CHOP shall be named as an additional insured within the other party's products liability insurance policies; provided, that such additional insured status will apply solely to the extent of the insured party's indemnity obligations under this Agreement. Waivers of subrogation and additional insured status obligations will operate the same whether insurance is carried through third parties or self-insured. Upon the other party's written request from time to time, each party shall promptly furnish to the other party a certificate of insurance or other evidence of the required insurance.

7. Use of CHOP Name.

Except as required by Section 11 herein, Customer shall not use the name, insignia, trademark, trade name, logo, abbreviation, nickname, or other identifying mark or term of CHOP for any purpose, except as required by law, without the prior written consent of CHOP's Chief Marketing Officer for each instance of use. Requests for such use shall be made to CHOP's Office of General Counsel at legal@chop.edu.

8. Invention and Patent Rights; Licenses.

8.1 *Ownership.* It is recognized and understood that all inventions and technologies owned by CHOP or Customer and existing on the effective date of this Agreement shall remain the separate property of CHOP or Customer, respectively. Such inventions and technologies are not affected by this Agreement and none of the parties shall have any claims or rights to or in such separate inventions or technologies of the other parties.

CHOP shall retain ownership of its proprietary operating procedures, know-how, manufacturing process(es), methods, and techniques as well as any and all new developments and improvements related to such processes, methods, and techniques made in the performance of this Agreement ("**CHOP Process**"). Customer will not use or disclose to any third party any confidential or proprietary information of CHOP without CHOP prior written consent, including without limitation any information Customer learns if Customer visits CHOP premises or without limitation any CHOP Process. Customer agrees that any information related to any CHOP Process that is (i) disclosed by CHOP to Customer or (ii) learned by Customer in its dealings with CHOP under this Agreement shall be treated as confidential, proprietary information of CHOP and that Customer shall not share such information with any third party or use such information for any purpose. To the extent that Customer is required to disclose any CHOP Process under applicable law, Customer shall notify CHOP no later than fifteen (15) days in advance of such disclosure, and Customer shall, to the extent permitted under applicable law, follow CHOP's advice and guidance with respect to the form and content of such disclosure

8.2 *Spark License.* In the event that CHOP manufactures Project Deliverables for human clinical studies, Customer understands and acknowledges that Spark Therapeutics, Inc. ("**Spark**") holds an exclusive license from CHOP for certain patents, know-how, and data, including the ability to reference CHOP's Drug Master File ("**DMF**") on file with the U.S. Federal Food and Drug Administration ("**FDA**"), for Commercial Purposes. Customer must secure a sublicense from Spark to allow the Project to move beyond the SOW attached hereto as **Exhibit A**. Customer shall be granted a limited right of cross reference to the DMF on file with the FDA solely for the purpose of supporting the project described in the SOW. For the avoidance of doubt, the SOW must be limited to manufacture for purposes that do not exceed in vitro studies, lab animal studies, Phase 1, Phase 1/2, and/or Phase 2 clinical trials, and must not include any use or manufacture for Commercial Purposes. Any extension of such SOW to include Project Deliverables for a clinical trial for the purpose of conducting a pivotal or registration trial or for commercial manufacture, or for any other Commercial Purposes shall not be permitted without a sublicense from Spark. In addition, no right of cross reference to the DMF is granted by CHOP for a clinical trial for the purpose of conducting a pivotal or registration trial or for commercial manufacture, or for any other Commercial Purposes. In the event of any conflict between a SOW and this Agreement, the terms of this Agreement shall prevail.

9. Export Control.

Customer shall not disclose or provide to CHOP or any CHOP trustee, officer, employee or agent of CHOP or other person in a position to receive such information from Customer (each a "**Customer PERSON**") any information subject to the licensing provisions of International Traffic In Arms Regulations (ITAR) under 22 CFR §§ 120-130, and Export Administration Regulations (EAR) under 15 CFR §§ 730- 774, or any other similar governmental authority or organization without limitation, without the prior written notice to and advance approval by CHOP. Customer shall not import or export and materials or information provided by CHOP to Customer without the appropriate license or approval from any applicable regulatory authority.

10. Publication.

Sponsor and CHOP agree that in the event CHOP manufactures a product that results in a scientific publication, (a) representative(s) from CHOP CVC will be included as co-author as deemed appropriate in accordance with standard, peer reviewed, academic practices for publications.

11. Hazardous and Regulated Material.

Customer shall package, label, transport, and ship hazardous materials, or material containing hazardous materials, and any other regulated materials, in accordance with all applicable federal, state, and local laws, rules, ordinances, and regulations, and shall furnish any appropriate documentation or Material Data Safety Sheets. Prior to each shipment of any hazardous regulated materials, Customer shall notify CHOP of the nature of such shipment by such means of communication as will allow for the proper preparation for acceptance of the delivery and shall identify same on all shipping documents. Customer shall be solely responsible for notifying carriers and other handlers of any risks inherent in any such shipments.

12. Fair Market Value; No Inducements.

Each Party represents that the compensation provided under this Agreement represents the fair market value of the services to be performed, has been negotiated in an arm's-length transaction, and has not been determined in any manner with regard to any implicit or explicit agreement to provide favorable procurement decisions with regard to the value or volume of any business or referrals generated between the parties.

13. Notices.

Any notice required or permitted to be given under this Agreement by any party shall be in writing and shall be (a) delivered personally, (b) sent by registered mail, return receipt requested, postage prepaid, (c) sent by a nationally-recognized courier service guaranteeing next-day or second day delivery, charges prepaid, or (d) delivered by email to the addresses of the other party set forth below, or at such other addresses as may from time to time be furnished by similar notice by any party. The effective date of any notice under this Agreement shall be the date of receipt by the receiving party.:

For Customer:

Orphion Therapeutics, Inc.
57 Meadow Woods Road
Great Neck, NY 11020
Attention: Jason S. Slakter, MD, CEO

For CHOP:

The Children's Hospital of Philadelphia
Roberts Center for Pediatric Research – 17th Floor
2716 South Street
Philadelphia, PA 19146
Attention: Vice President, Technology Transfer, Commercialization and Innovation
Email: SUNLEAFS@EMAIL.CHOP.EDU

With a copy to:

The Children's Hospital of Philadelphia
Office of General Counsel
Roberts Center for Pediatric Research – 20th Floor
2716 South Street
Philadelphia, PA 19146
Email: legal@chop.edu

Either party may change its address for notice by giving notice thereof in the manner set forth in this Section 13.

14. Limited Storage of Customer Material.

The parties acknowledge that CHOP has limited storage space, and that after the product release, CHOP

agrees to store the Customer Material and/or Project Deliverables for up to six (6) months after the date of the product release. Customer shall communicate to CHOP as soon as practicable where to ship the Customer Materials and/or Project Deliverables. Such Customer Materials and/or Project Deliverables cannot be stored by CHOP for a period longer than six (6) months from the date of the product release without Customer incurring additional costs in the amount of $260 per month. Any storage by CHOP of any Customer Material and or Project Deliverables for a period loner than six (6) months from the date of product release ("**Extended Storage**"), shall not last more than the third anniversary of the product release date. Any Extended Storage shall require a written agreement which shall address the Extended Storage period and costs to be charged by CHOP to Customer for such Extended Storage. Customer shall reimburse CHOP for additional storage costs whether the costs are for Extended Storage or otherwise. CHOP may also, at its sole discretion, place Customer Material and/or Project Deliverables in an off-site storage facility qualified by CVC for GMP storage and Customer shall reimburse CHOP for any fees for such storage. During the Term, CVC may periodically notify Customer in writing to request disposition of Customer Material or Project Deliverables, upon completion of project stages ("**Notified Customer Material**"). Upon request, Customer agrees to provide written instructions with respect to the Notified Customer Materials within forty-five (45) days. If Customer wishes to retain any of the Notified Customer Material, CVC shall deliver such Notified Customer Material in accordance with the instructions provided by the Customer. Shipping charges for shipment of Customer Material and/or Project Deliverables to a single destination defined by Customer, are included in the project cost. If Customer fails to respond to the notice or indicates in writing it does not wish to retain Notified Customer Material, all rights, title and ownership to such Notified Customer Material shall automatically transfer to CVC without further consideration to Customer and Customer shall have no further interest therein. Upon such transfer, CVC shall be entitled to dispose of the Notified Customer Material, notwithstanding any other provisions herein.

15. *General Provisions*

15.1 *Laws and Regulations*. This Agreement is subject to all local, state and federal laws and regulations. In carrying out the purpose of this Agreement, each of CHOP and Customer agrees that its activities will be conducted in compliance with all relevant laws and regulations in force at the United States federal, state and local levels. Customer shall also conform to the requirements and standards of the Association for Assessment and Accreditation of Laboratory Animal Care International in all activities of the Project undertaken by Customer. This Agreement is governed by the laws of the Commonwealth of Pennsylvania. Any legal action involving or arising under this Agreement or the Project Deliverables will be adjudicated in the courts of the Commonwealth of Pennsylvania, located in Philadelphia, Pennsylvania without regard to its conflict of laws principles. Customer represents and warrants that neither Customer nor its affiliates nor any director, officer, agent, or employee of Customer is currently subject to any sanctions administered by any government authority or agency.

15.2 *Assignment.* Customer may transfer or assign its rights and obligations under this Agreement, without consent if such assignment is a Qualified Assignment to an affiliate or a successor to all or substantially all of its business or assets relating to this Agreement, whether by sale, merger, operation of law, or otherwise, provided that, in the event of such sale or merger, such assignment is a "Qualified Assignment" and that Customer notifies CHOP within ten (10) days of any Qualified Assignment, and Customer provides CHOP a copy of such assignment (subject to redaction of any financial or confidential parts of the assignment document or other parts of the assignment document that relate to assets or parts of the business that are not relevant to this Agreement).

For the purposes of this Agreement, a "Qualified Assignment" means any assignment that:

(a) is made in compliance with applicable laws;
(b) includes the assignee's written acknowledgement of and written agreement to all of Customer's obligations under the Agreement;

(c) is made to an assignee that is, and will be after giving effect to the relevant assignment, Solvent;
(d) is made to an assignee that is not subject at the time of such assignment to any order, decree or petition providing for (i) the winding-up or liquidation of such person, (ii) the appointment of a receiver over the whole or part of the assets of such person or (iii) the bankruptcy or administration of such person;
(e) is not a voidable fraudulent conveyance;
(f) is made to an assignee that is at the time of such assignment not debarred under 21 U.S.C. §30 or under investigation or threatened to be debarred under 21 U.S.C. §30; and
(g) will not cause a material increase in taxes, costs or expenses to CHOP other than as a result of increased income to CHOP (unless the assignee has agreed to compensate CHOP for the same).

For purposes of this Section 15.2, "**Solvent**" means, with respect to any person as on any date of determination, that as of such date, (i) the value of the assets of such person is greater than the total amount of liabilities (including contingent and unliquidated liabilities) of such person, (ii) such person is able to pay all liabilities of such person as such liabilities mature and (iii) such person does not have unreasonably small capital (taking into account such person's obligations hereunder). In computing the amount of contingent or unliquidated liabilities at any time, such liabilities shall be computed at the amount that, in light of all the facts and circumstances existing at such time, represent the amount that can reasonably be expected to become an actual or matured liability.

Except as provided herein, the Customer and CHOP agree that their rights and obligations under this Agreement may not be transferred or assigned without the prior written consent of the other party hereto, which consent may be withheld in such other party's sole discretion.

Notwithstanding anything to the contrary in this Section 15.2 or elsewhere in this Agreement, CHOP may sell, transfer or assign its rights to any third party to receive payments under this Agreement, and CHOP may disclose Confidential Information of Customer to one or more third parties (provided such third part is under obligations of confidentiality to CHOP at least as stringent as those in this Agreement) in connection with any such assignment to enable the third party(ies) to evaluate and monitor any such purchase.

Any attempted assignment, delegation or transfer in violation of this Section 15.2 will be void. Any permitted assignee will assume all assigned obligations of its assignor under this Agreement. The terms and conditions of this Agreement will inure to the benefit of, and be binding upon, the legal representatives, successors and permitted assigns of the parties to this Agreement.

15.3 *Severability.* If any provision of this Agreement becomes or is declared illegal, invalid, or unenforceable, the provision will be divisible from this Agreement and deemed to be deleted from this Agreement. If the deletion substantially alters the basis of this Agreement, the parties will negotiate in good faith to amend the provisions of this Agreement to give effect to the original intent of the parties.

15.4 *Independent Contractors.* CHOP and Customer are independent contractors and neither is an agent, joint venturer, or partner of the other. No employee of CHOP may be listed by Customer as an investigator or co-investigator under this Agreement without the express written approval of CHOP.

15.5 *Prevailing Terms.* In the event of any inconsistency between the terms of this Agreement and the documents referenced or incorporated into this Agreement, the terms of this Agreement prevail.

15.6 *Entire Agreement and Electronic Signature.* This Agreement, the SOW, QMP 026, and other pertinent documentation attached hereto represents the entire agreement and understanding between the parties with respect to its subject matter. It supersedes all prior or contemporaneous discussions, representations, or agreements, whether written or oral, of the parties regarding this subject matter. This Agreement may be

executed in two or more counterparts, each of which will be deemed an original, and all of which together will constitute the same agreement. This Agreement may be executed by a party through electronic means, and copies of this Agreement executed and delivered by means of electronic signatures shall have the same force and effect as if such signatures were originals. Delivery of an executed copy of this Agreement by any party via electronic transmission will be as effective as delivery of a manually executed copy of the Agreement.

15.7 *Waiver.* The waiver by either party of a breach of any provision of this Agreement shall not operate as or be considered a waiver by that party of any subsequent breaches.

15.8 *Amendments or Changes.* Amendments or changes to this Agreement must be in writing and signed by the parties' authorized representatives.

15.9 *Force Majeure.* CHOP shall not be liable or responsible to the other party, nor be deemed to have defaulted under or breached this Agreement, for any failure or delay in fulfilling or performing any term of this Agreement, when and to the extent such failure or delay is caused by or results from acts beyond CHOP's control, including but not limited to, the following force majeure events ("**Force Majeure Event**(s)"): acts of God; flood, fire, earthquake, healthcare crises including pandemic, explosion, war, invasion, hostilities (whether war is declared or not), terrorist threats or acts, riot or other civil unrest, government order, law, or actions, emergency declarations, embargoes or blockades in effect on or after the date of this Agreement, national, state or regional emergency, strikes, labor stoppages or slowdowns or other industrial disturbances, shortage of adequate power or transportation facilities; and other events similar to those listed in this Section 15.9 that are beyond the control of CHOP.

15.10 *Conflicts and Ethical Standards of Conduct.* Customer affirms that, to the best of Customer's knowledge, there exist no conflicts of interests between Customer and CHOP or its employees. Customer hereby represents that it has neither received nor given gifts or gratuities to any member of the CHOP community, nor participated in any other unethical conduct in connection with this Agreement. If, at any time, CHOP determines that Customer is in violation of any representation under this Section 15.10, CHOP may cancel this Agreement upon written notice to Customer, and CHOP shall have no further obligation to Customer.

15.11 *Equal Opportunity Employer.* CHOP is an Equal Opportunity Employer. If applicable, CHOP and Customer shall abide by the requirements of 41 CFR 60-300.5(a). This regulation prohibits discrimination against qualified protected veterans, and requires affirmative action by covered prime contractors and subcontractors to employ and advance in employment qualified protected veterans. If applicable, CHOP and Customer shall abide by the requirements of 41 CFR 60-741.5(a). This regulation prohibits discrimination against qualified individuals on the basis of disability, and requires affirmative action by covered prime contractors and subcontractors to employ and advance in employment qualified individuals with disabilities. Customer warrants that it will not discriminate in the performance of this Agreement or employment against any person because of age, race, color, religion, national or ethnic origin, sex, sexual orientation, gender identity, marital status, veteran status, or disability. Customer also warrants that it will comply with all applicable executive orders, and federal, state, and local laws, regulations, and rules, relating to nondiscrimination, equal employment opportunity, and affirmative action. This Section 15.11 will not prevent Customer from designing and administering clinical trials that may include or exclude persons of a particular age, race, color, religion, national or ethnic origin, sex, sexual orientation, gender identity, marital status, veteran status, or disability as necessary for the design of the clinical trial and consistent with any applicable law.

15.12 *Survival.* The rights and obligations of each of CHOP and Customer, which by intent or meaning have validity beyond any termination or expiration of this Agreement, shall survive such termination or expiration of this Agreement, including but not limited to Sections 1.3, 2.2, 3 and 4 (in each case of 3 and 4, only with respect to any outstanding payment obligations), 5, 6, 7, 8, 9, 10, 11, 13, 14, and 15.

15.13 *No Presumption Against Drafter*. For purposes of this Agreement, Customer hereby waives any rule of construction that requires that ambiguities in this Agreement (including any Exhibit, attachment, schedule or other appendix hereto) be construed against the drafter.

Remainder of page intentionally left blank.
Signature page follows.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed as of the last date written below.

THE CHILDREN'S HOSPITAL OF PHILADELPHIA

DocuSigned by:

By _____
BB6FD149A73F422...

Name: Zev Sunleaf

Title: Vice President-TTIRC

Date: 12/15/2020

Orphion Therapeutics, Inc.

DocuSigned by:
Jason Slakter

By _____
03E939FF5D7641B...

Name: Jason S. Slakter, MD

Title: Chief Executive Officer

Date: 12/15/2020

EXHIBIT A

DESCRIPTION OF RESEARCH

GLP Fill/Finish of a pre-exiting GMP-grade Bulk Drug Substance and custom testing.

SCOPE OF WORK AND PROJECT DELIVERABLES:

1) AAV2-TPP1 bulk drug substance (BVA2B1-1804C-A) will be filled as a Research Grade product manufactured using a GMP-comparable process to support GLP Pharm/Tox studies. GLP Product will be filled at 0.25 mL/vial at target titer of 2e12 vg/mL. Note: test samples will be taken after bulk thaw. However, product will be filled at-risk without delay without bulk testing results being available.

2) Additional Bulk testing includes:
    a. Identity: Appearance by Visual Inspection
    b. Safety: Bioburden by Direct Plating
    c. Safety: Bacterial Endotoxin by LAL kinetic Chromogenic Method
    - Potency: Vector Genome Titer by Q-PCR
    - Purity: OD260/280 by spectrometry
    - Purity: SDS PAGE/Silver Stain

3) Standard GLP FP release testing includes:
    - Identity: Appearance by Visual Inspection
    - Safety: Bacterial Endotoxin by LAL kinetic Chromogenic Method
    - Potency: Vector Genome Titer by Q-PCR (vg/mL)
    - Purity: OD260/280 by spectrometry
    - Purity: SDS PAGE/Silver Stain

4) Additional custom FP release testing includes:
    - Safety: Isolator Sterility USP, EP, JP
    - Safety: Isolator Sterility suitability
    - Identity: pH by Potentiometry
    - Identity: Osmolality by Osmometry
    - Identity: Vector Genome Identity by Sequencing
    - Safety: Replication Competent AAV by ITR-REP Q-PCR (Copies/10^9 vg)
    - Purity: Capsid/vg ratio by Spectrophotometry (cp/vg)
    - Purity: Residual Host Cell Proteins by ELISA (pg/10^9 vg)
    - Purity: Residual Bovine Serum Albumin (BSA) by ELISA (pg/10^9 vg)
    - Purity: Residual Benzonase by ELISA (pg/10^9 vg)
    - Purity: Residual Host Cell DNA by Q-PCR (pg/10^9 vg)
    - Purity: Residual Plasmid DNA by Q-PCR (pg/10^9 vg)
    - Purity: Residual Cesium by Mass Spectrometry
    - Purity: Residual E1A DNA by Q-PCR (Copies/10^9 vg)

    Note: Infectious titer is the responsibility of the sponsor and is not included

5) 50 vials of non-clinical excipient (no additional testing)

6) Statement of Work and Cost Estimate (Estimate 111920-01) attached (Appendix A).

7) CHOP will provide Customer with a Certificate of Characterization (CoC). Template for standard GLP CoC attached in Exhibit A, Appendix B (*Note: actual CoC will be modified to include custom test results in addition to standard testing as listed above*).

8) CMC support for IMPD submission includes QA and management support for LRF review (3 days), regulatory audit (3 days), and other support per email or conference call as required, the latter not exceeding 40 hours in aggregate.

PAYMENT SCHEDULE:

Milestone 1: Acceptance of SOW (33%; Non-Refundable) $55,831
Milestone 2: Completion of Fill (33%) $55,831
Milestone 3: Competion of Testing Results (Remaining Balance) $55,830

IN WITNESS WHEREOF, the parties hereto have caused this SOW to the Agreement to be duly executed as of the last date written below.

THE CHILDREN'S HOSPITAL OF PHILADELPHIA

DocuSigned by:
By _____
BB6FD149A73F422...
Name: Zev Sunleaf
Title: Vice President-TTIRC
Date: 12/15/2020

ORPHION THERAPEUTICS, INC.

DocuSigned by:
Jason Slakter
By _____
03E939FF5D7641B...
Name: Jason S. Slakter, MD
Title: Chief Executive Officer
Date: 12/15/2020

Appendix A – Cost Estimate

"Exhibit A"
"Statement of Work"

The Children's Hospital of Philadelphia® RESEARCH INSTITUTE

CENTER FOR CELLULAR & MOLECULAR THERAPEUTICS

DATE: 11/19/20

ESTIMATE : 111920-01

SERVICE PROVIDER	CUSTOMER
Clinical Vector Core **Center for Cellular & Molecular Therapeutics** The Children's Hospital of Philadelphia 3501 Civic Center Boulevard Philadelphia, PA 19104 Phone: (267) 425-2011 E-mail: vanderlooj@email.chop.edu	Jason Slakter, MD **Orphion Therapeutics, LLC** 111 Great Neck Road, Suite 300 Great Neck, NY 11021 Phone: (917) 951-5659 E-mail: Jason.Slakter@orphiontherapeutics.com

DESCRIPTION
AAV2-TPP1 bulk drug substance (BVA2B1-1804C-A) will be filled as a Research Grade product using a GMP-comparable process to support GLP Pharm/Tox studies. GLP Product will be filled at 0.25 mL/vial at target titer of 2e12 vg/mL. Standard GLP final product release testing includes Appearance, Endotoxin, Titer by qPCR, Purity by OD260/280 and SDS PAGE/Silver Stain. Includes additional testing for bulk and FP as indicated in the SOW. Includes 50 vials of non-clinical excipient (no additional testing).

Grade: GLP

Variable Cost	Batches	Weeks	Cost Each	Total Cost
Facility/Equipment		1	$ 1,687	$ 1,687
Fixed Cost	**Lot**	**Weeks**	**Cost Each**	**Total Cost**
Bulk Substance (BVA2B1-1804C-A)	1		$ 25,000	$ 25,000
Labor	1		$ 37,086	$ 37,086
Materials	1		$ 627	$ 627
Fill & Finish	1		$ 713	$ 713
Release Testing	1		$ 17,527	$ 17,527
Shipping & Handling	1		$ 3,600	$ 3,600
Other	**Each**	**Weeks**	**Cost Each**	**Total Cost**
CMC Support	1		$ 42,100	$ 42,100
Insurance	0		$ 16,998	$ -
Excipient non-clinical (1 mL/vial)	50		$ 10	$ 500

Direct Cost	$	128,840
Hospital Surcharge (Industry Rate)	$	38,652
Total	**$**	**167,492**

Estimate valid until 5/18/21

APPENDIX B

Children's Hospital of Philadelphia RESEARCH INSTITUTE

RAYMOND G. PERELMAN CENTER FOR CELLULAR & MOLECULAR THERAPEUTICS

Clinical Vector Core, 3501 Civic Center Boulevard, Philadelphia, PA 19104 Tel. 267-425-2011

Certificate of Characterization
Non-Clinical Product

Product Name:	**Vector Name**
Lot Number:	**Lot Number**
Manufactured by:	Clinical Vector Core, CCMT, CHOP
Date of Manufacture:	DDMMMYYYY
Container/Closure:	Manufacturer/ Part Number
Fill Volume:	___ mL
Lot size:	Number of vials filled
Formulation:	180mM NaCl 10mM Na Phosphate, 0.001% Poloxamer 188
Storage:	< - 60 °C

Attribute/Test/Method	***Testing Facility/ Procedure ID/ Test ID***	***Specification***	***Result***
Identity: Appearance by Visual Inspection	CCMT QC047 Assay ID	Clear, colorless solution. No visible particulates.	
Safety: Bioburden by Direct Plating	CCMT QC034 Assay ID	No Growth	
Safety: Bacterial Endotoxin by LAL kinetic Chromogenic Method	CCMT QC035 Assay ID	< 5 EU/mL	
Potency: Vector Genome Titer by Q-PCR	CCMT QC011 Assay ID	Report Result	
Purity: A_{260}/A_{280} by Spectrophotometry	CCMT QC121 Assay ID	$\geq$ 1.3	
Purity: SDS PAGE/Silver Stain	CCMT QC026 Assay ID	Comparable to AAVN Reference	

_____ _____
Quality Assurance, Clinical Vector Core Date

_____ _____
Quality Director, Clinical Vector Core Date

EXHIBIT D

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK: COMMERCIAL DIVISION PART 53

----------X

ORPHION THERAPEUTICS, INC.,

Plaintiff,

- v -

THE CHILDREN'S HOSPITAL OF PHILADELPHIA, LATUS BIO, INC.,BEVERLY L. DAVIDSON,

Defendant.

INDEX NO. 655222/2024

MOTION DATE 12/18/2024, 12/17/2024, 12/17/2024, 12/17/2024

MOTION SEQ. NO. 001 002 002 003

DECISION + ORDER ON MOTION

----------X

HON. ANDREW BORROK:

The following e-filed documents, listed by NYSCEF document number (Motion 001) 16, 17, 18, 27, 31, 32, 33, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 70, 95

were read on this motion to/for DISMISSAL.

The following e-filed documents, listed by NYSCEF document number (Motion 002) 19, 20, 21, 28, 34, 35, 36, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 71, 96, 97

were read on this motion to/for DISMISS.

The following e-filed documents, listed by NYSCEF document number (Motion 002) 19, 20, 21, 28, 34, 35, 36, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 71, 96, 97

were read on this motion to/for DISMISSAL.

The following e-filed documents, listed by NYSCEF document number (Motion 003) 23, 24, 25, 26, 29, 30, 37, 38, 39, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 89, 94

were read on this motion to/for DISMISS.

Upon the foregoing documents and for the reasons set forth on the record (*tr.* 5.9.25), the motions to dismiss are granted solely to the extent that Orphion shall file an amended complaint in accordance with the rulings set forth on the record no later than June 20, 2025.

Accordingly, it is hereby

ORDERED that the motions (Mtn. Seq. Nos. 001-003) are GRANTED solely to the extent set forth on the record (*tr.* 5.9.25); and it is further

ORDERED that Orphion shall file an amended complaint in accordance with the rulings set forth on the record by June 20, 2025; and it is further

ORDERED that the parties are directed to order and upload a copy of the transcript (*tr.* 5.9.25) to NYSCEF, and the parties shall split the cost of the transcript.

[redacted]

5/9/2025
DATE

CHECK ONE:		CASE DISPOSED			X	NON-FINAL DISPOSITION	
		GRANTED		DENIED	X	GRANTED IN PART	OTHER
APPLICATION:		SETTLE ORDER				SUBMIT ORDER	
CHECK IF APPROPRIATE:		INCLUDES TRANSFER/REASSIGN				FIDUCIARY APPOINTMENT	REFERENCE

EXHIBIT E

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK - CIVIL TERM - PART 53

Orphion THERAPEUTICS, INC.,

Plaintiff,

- against -

THE CHILDREN'S HOSPITAL OF PHILADELPHIA; LATUS BIO, INC.; and BEVERLY L. DAVIDSON,

Defendants.

INDEX NUMBER: 655222/2024

Proceedings

60 Centre Street
New York, New York
May 9, 2025

B E F O R E :

HONORABLE ANDREW BORROK,

JUSTICE OF THE SUPREME COURT

A P P E A R A N C E S :

SADIS & GOLDBERG LLP
Attorneys for the Plaintiff
551 Fifth Avenue, 21st Floor
New York, New York 10176
BY: BEN HUTMAN, ESQ.
JENNIFER ROSSAN, ESQ.
JAMES ANCONE, ESQ.

MORGAN LEWIS
Attorneys for the Defendant
THE CHILDREN'S HOSPITAL OF PHILADELPHIA
101 Park Avenue
New York, New York 10178
BY: JOHN V. GORMAN, ESQ.
GRANT R. MACQUEEN, ESQ.

A P P E A R A N C E S: (continued)

GOODWIN PROCTER LLP
Attorneys for the Defendants
LATUS BIO, INC. and BEVERLY L. DAVIDSON
620 Eighth Avenue
New York, New York 10018
BY: JEFFREY A. SIMES, ESQ.

ANNE BROWN, RPR
SENIOR COURT REPORTER

disputes. I start from that premise. The parties are free to contract in any way they want and it's incumbent upon the Courts to enforce parties' agreements. That's the premise that I start with. The license agreement designated New York, and in that agreement as it relates to the subject matter of that particular agreement, they said, "We're going to fight -- if we have to fight at all -- in New York."

When they entered into a purchase agreement -- which you've told me now does not include the subject matter of the license agreement -- they said as it relates to items that are set forth in the purchase agreement. If there's a dispute arising under the purchase agreement, they designated a different forum as it relates to disputes which arise under that particular agreement.

It's not that it modified the other agreement. They just said, "As it relates to the issues which arise under the purchase agreement, we're going to Philadelphia for those issues."

MR. GORMAN: Those two clauses are in contradiction of each other, Your Honor.

THE COURT: I'm not so sure I agree with that argument is what I'm trying to say to you. There are different -- these agreements covered different subject matter.

MR. GORMAN: Well, I'll agree with you that the

MR. HUTMAN: We can. We can. No. When we drafted the complaint we put all breach of contract in one cause of action, but that doesn't have to be that way.

THE COURT: Well, are you asking me to file an amended complaint?

MR. HUTMAN: I'm saying to the extent Your Honor finds that because the cause of action covers both agreements, the entire cause of action goes over there, as opposed to just the portion that's about the purchase agreement. We can file an amended complaint to isolate out the license agreement from the purchase agreement.

THE COURT: I think you can tell from the robust conversation that I had with the lawyer from CHOP that I am of the view that the parties designated claims which arise under the purchase agreement to be governed by the purchase agreement, and the designation in the purchase agreement that claims arising under that agreement have to be litigated in the Commonwealth of Pennsylvania.

What that lawyer said to me, as you heard, is that they are of the view that every single one of your claims arise under the purchase agreement and none of them arise under the license agreement. So to the extent that you are of the view that you have claims that arise under the license agreement, where the forum selection clause continues to apply, that's set forth in the license

THE COURT: Okay?

MR. SIMES: Thank you, Your Honor.

THE COURT: Okay. I got five okays. I'll leave it at five. Thank you for today.

* * *

The foregoing is hereby certified to be a true and accurate transcript of the proceedings as transcribed from the stenographic notes.

ANNE BROWN, RPR
SENIOR COURT REPORTER